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An Exploratory Study of Functional Status in Post Cardiac Arrest Survivors Discharged To Home

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UNIVERSITY OF SAN DIEGO Hahn School of Nursing and Health Science DOCTOR OF PHILOSOPHY IN NURSING

AN EXPLORATORY STUDY OF FUNCTIONAL STATUS IN POST CARDIAC ARREST SURVIVORS DISCHARGED TO HOME

By

John J Whitcomb

A dissertation presented to the

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Abstract

Cardiopulmonary arrest is a major health problem claiming 350,000 to 450,000 lives per year in the United States, but survival has increased to 49% from the use of Automated External Defibrillators (AED) by lay personnel. Leidy's work on functional status is a comprehensive framework to describe functional status and has not been used in this population.

The specific aims of the project were to describe perceived functional capacity, physical functional performance, mental health, symptom distress, and demographic factors in survivors of cardiopulmonary arrest after discharge to home and to examine the relationship among perceived functional capacity, mental health and physical functional performance in the survivor of cardiopulmonary arrest after discharge to home.

This study used a convenience sample, with a mixed method descriptive correlation design to determine the relationships among the study variables. As a comparison group non-cardiac arrest post myocardial infarction subjects actively engaged in cardiac rehabilitation were recruited. Three qualitative questions were added to further explore the quantitative findings of the study increasing the richness of the study. Overall significant findings suggested that in the cardiac arrest group, symptom distress had a negative influence in the ability to participate in social activities and roles at work or within family settings. Symptom distress also had an inverse relationship in the total number of daily steps taken, as symptom distress increased, daily average steps decreased suggesting that control of symptoms such as nausea and fatigue are important factors in functional status and mental health in this sample.

In the non-cardiac arrest group, physical functioning, the ability to perform physical activities, had a positive influence in their control of symptom distress, participation in social activities and role perception, suggesting that an increased number of daily steps taken increases participation in social activities and increases role perception. This finding was supported by the fact the non-cardiac arrest group was actively engaged in a cardiac rehabilitation program twice a week for eight weeks. In this study it was demonstrated there are multiple variables that impact one's functional status and it is imperative that healthcare providers seek and understand the most important factors that influence one's perceived functional status and mental health as this has significant importance in the cardiac arrest survivor's recovery.

Dedication

This project is dedicated to all the cardiac arrest survivors and those who have a second chance at life.

Preface

People have asked why I became interested in this topic and the answer has always remained the same: very few of us have a second chance at life. It occurred to me one day when I had a patient who had a cardiac arrest; I guided the resuscitation for the patient, which required CPR and defibrillation. I thought nothing of it, as it was part of the job as a critical care nurse. When I came in the following day and saw the patient from the previous day sitting in the chair eating breakfast surrounded by his family, he had a smile on his face and that's when it hit me: he has a second chance at life.

I always reflected on this event in class as projects came about and it was Dr Orsi who I saw as the person to get me where I needed to be to critically look at this phenomenon. After numerous meetings, suggestions and encouragement the project took form. He is a man of integrity and foresight always keeping the task at hand, in perspective and when I would become too narrow minded he would say, "Cast the net wide." Our meetings always ended with a little bit of humor and a smile knowing there was much more to come and he would always say, "Remember it's a journey."

My sincere thank-you to Dr Georges, as she always had words of encouragement and a gentle smile that always calmed the waters when it seemed the waters were too rough to sail.

I am deeply grateful to Dr Roth, as she was one of my first contacts at the University of San Diego and left an impression that will forever be imprinted on my professional soul. She would always provide guidance, words of encouragement and was the contact for my wife when I was deployed to Iraq for Operation Enduring Freedom. Her support and the support of all the professors at the University during those trying times for me and my family are immeasurable, as if it was not for their support I would not have finished my degree.

I am forever grateful and indebted to Dr Major King, Captain, Nurse Corps, United States Navy, (Retired), for the insights he gave me during this project. His vast experience in research, concept analysis, weekly guidance and structure provided me the framework needed to become a nurse scientist and Dr King let us not forget all the meetings we had at Starbuck's.

I cannot thank Donna Agan enough for her assistance in the initial statistical analysis, editing and manuscript preparation of this project. It was always nice to have her say "How's it going?" with a big smile.

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And finally, to my beautiful family: My wife Kathy, my daughter Krista and my in-laws, Layne and Dianne Brown. You have been there to support my military career and this project. Making sacrifices to ensure I had what I needed, for understanding when I had to be away at classes, not attending all the family events, and the many days when it seemed I was there in body but I was thinking or formulating ideas about this project and supporting me while I was deployed then returning to find myself catching up on lost time. This degree is not only mine but yours as well! I love you all and could not have finished without your presence.

Table of Contents

Approval Page ii
Abstract iii
Copyright v
Dedication vi
Preface vii
Table of Contents ix
List of Tables xi
List of Appendices xii
Chapter 1: Introduction 2
Introduction Background 2
Functional Status: Leidy's Theoretical Framework 4
Functional Status Post Cardiopulmonary Arrest 7
Purpose and Aims 9
Theoretical Definitions 9
Chapter 2: Review of Literature 11
Quality of Life 12
Functional Capacity 13
Functional Performance 15
Functional Reserve 17
Functional Capacity Utilization 18
Varied Interpretations of Functional Status 20
Issues of Measurement 21
What is Known 24
Research Variables of Interest for this Study 24
Non-Cardiac Arrest, Post Myocardial Infarction Group 25
Perceived Functional Capacity 25
Physical Functional Performance 25 Symptom Distress 26
Symptom Distress 26 Demographics 26
Mental Health 27
Summary 28
Chapter 3: Methods 30
Research Design 30
Sample 32
Facilities for Data Collection 34
Operational Definitions of Variables and Instrumentation 34
Mini-Mental State Exam 34
SF-36 Health Survey 36
Perceived Functional Capacity 38

Physical Functional Performance 39 Symptom Distress 42 Demographics 43 Mental Health 43 Data Collection Procedures 44 Order of Administration of Measures 44 Data Collection and Recording 45 Data Processing and Analysis 47 *Limitations of the Study* **48** Subjects Risk and Benefits 49 Chapter 4: Results 52 Sample 52 Instrument Reliability and Validity 56 Data Analysis 59 Multiple Regression **69** Chapter 5: Findings 76 Summary **76** Perceived Functional Capacity Cardiac Arrest Group 78 Mental Health Cardiac Arrest Group 80 Perceived Functional Capacity Non-Cardiac Arrest Group 81 Mental Health Non-Cardiac Arrest Group 81 Physical Functional Performance 82 Symptom Distress 83 Symptom Distress Cardiac Arrest Group 84 Symptom Distress Non-Cardiac Arrest Group 84 Predicting Functional Status in Post Cardiac Arrest Survivors 85 Study Reliability and Validity **86** Reliability of Measures in Cardiac Arrest Survivors 86 Internal Validity 88 Usefulness of Model 90 Conclusions 91

References **95**Appendices **100**

Recommendations for Future Research 92

List of Tables

Tables Table 1	Interpretation of Mini-Mental State Exam Based on Age and Education 36
Table 2	Reason for Subject Exclusion 52
Table 3	Subject Demographics 54
Table 4	Weight and Body Mass Index for Study Sample 55
Table 5	Average Number of Steps 56
Table 6	Instrument Reliability in Study Population 57
Table 7	Normative Data Means and SD Perceived Functional Capacity (PCS Score) 58
Table 8	Normative Data Means and SD Mental Health (MCS Score) 58
Table 9	Normative Data Means and SD Symptom Distress 59
Table 10	Spearman's Rho Correlation Coefficients Cardiac Arrest Group PCS and MCS 61
Table 11	Spearman's Rho Correlation Coefficients Cardiac Arrest Group (Perceived Functional Capacity) 62
Table 12	Spearman's Rho Correlation Coefficients Cardiac Arrest Group (Mental Health) 64
Table 13	Spearman's Rho Correlation Coefficients Non-Cardiac Arrest Group PCS and MCS 65
Table 14	Spearman's Rho Correlation Coefficients Non-Cardiac Arrest Group (Perceived Functional Capacity) 67
Table 15	Spearman's Rho Correlation Coefficients Non-Cardiac Arrest Group (Mental Health) 69
Table 16	Regression Analysis of Cardiac Arrest Group Perceived Functional Capacity Steps as Dependent Variable 71
Table 17	Regression Analysis of Non-Cardiac Arrest Group Perceived Functional Capacity Steps as Dependent Variable 72

List of Appendices

Appendices

Appendix A Functional Status Framework 100

Appendix B Assessment of Quality of Life Outcomes 101

Appendix C Quality of Life Diagram 102

Appendix D SF-36 Scale 103

Appendix E SF-36 Health Survey **104**

Appendix F Symptom Distress Scale **106**

Appendix G Mini-Mental State Exam 109

Appendix H Demographics Questionnaire 111

Appendix I Qualitative Interview Cardiac Arrest Subjects 114

Appendix J Qualitative Interview Non-Cardiac Arrest Subjects 116

Appendix K IRB Approval University of San Diego 118

Appendix L IRB Approval Sharp Cardiac Rehabilitation Center 119

Appendix M Consent Form University of San Diego 120

Appendix N Consent Form Sharp Cardiac Rehabilitation Center 121

Appendix O California Experimental Subjects Bill of Rights 127

Running head: CARDIOPULMONARY ARREST SURVIVOR An Exploratory Study of Functional Status in Post Cardiac Arrest Survivors Discharged To Home John J. Whitcomb University of San Diego

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CHAPTER 1

The Problem

Introduction and Background

Cardiopulmonary arrest is a major health problem claiming 350,000 to 450,000 lives per year in the United States alone and is responsible for more than one-half of all deaths that are due to cardiovascular disease (Callans, 2004). The most common underlying cause of sudden cardiac arrest is an abrupt disorganization of the heart's rhythm, called ventricular fibrillation that can be triggered by a heart attack or can represent a catastrophic rhythm disturbance. Poor survival rates are related to the lack of implementation of the *Chain of Survival*, defined by the American Heart Association as early access, early CPR, early defibrillation, and early advanced cardiac life support (Bunch, White, Gersh, Meverden, Hodge, Ballman et al., 2003).

Legislative interest was shown when the House of Representatives passed H.R. 2984, the Cardiac Arrest Survival Act 2000 amending the Public Health Service Act, providing recommendations to the Secretary of Health and Human Services for the placement of AEDs in Federal buildings to improve survival rates of individuals who experience cardiac arrest in such buildings. Secondly, the act established protection from civil liability arising from the emergency use of the devices.

Training programs focusing on early defibrillation, such as Advanced Cardiac Life Support (ACLS) and the use of AEDs used by lay personnel; have improved the rate of survival from 5% to 45% in cardiopulmonary arrest patients. This was demonstrated in Rochester, Minnesota, where early defibrillation by police was implemented in late 1990 (Bunch et al. 2003). The rate of survival to hospital discharge with the use of the AED

was 40%. According to the American Heart Association (2002) there are no reliable national statistics on survival from cardiopulmonary arrest, as reporting varies from each treatment facility within the United States and does not allow for a comprehensive reporting system. However, the National Registry for Cardiopulmonary Resuscitation does provide a means of uniformly collecting cardiopulmonary arrest data, but this is limited to access to facilities that register with the organization and pay fees associated with the service. It is intended for quality improvement for facilities to compare their results with facilities similar in size and population.

The National Heart, Lung, and Blood Institute is conducting a study, Home Automatic External Defibrillator Trial (HAT), with a central hypothesis that provision of an AED for home use will improve survival beyond that achieved from the typical lay response to sudden cardiac arrest. In the Public Access Defibrillator Trial, volunteers were recruited in community units (e.g., shopping malls, apartment complexes); the units were randomly assigned to an emergency-response system involving volunteers trained in CPR or CPR plus the use of AEDs. Investigators found that the use of AEDs increased survival to hospital discharge without a decrement in the neurological function of survivors (Hallstrom & Ornato, 2004). With advances in training and technology available to medical and lay individuals, cardiopulmonary arrest is becoming a more survivable event but there is a lack of knowledge regarding a survivor's ability to live a normal life after the arrest.

A review of the literature revealed moderate evidence regarding quality of life in those who survived a cardiopulmonary arrest but it did not describe functional status.

Studies measuring functional status have used the concept of quality of life

interchangeably with functional status or used other variables as a measurement of functional status. For example, using neurological outcome to determine functional status by using the five point cerebral performance categories (CPC) classifications scores by Graves, Herlitz, Bang, Axelsson, Ekstrom, Holmberg, et al. (1997). In a study by Nick, Williams, and Barker (1998), the researchers measured functional independence on admission and discharge to rehabilitation facilities to determine and measure functional status. LaPier (2003) used physical endurance based upon physiological measurements to determine functional status post coronary artery bypass surgery.

The literature shows gaps in the measurement and blurred conceptualization of functional status. Given the prognostic importance of functional status measures, the results highlight the importance of developing a reliable and efficient means of obtaining a measure of functional status resulting in the advancement of nursing science. Having a clear and concise measure of functional status will enable clinicians to implement effect treatment plans that would lead to a faster recovery, higher level of functional status and a greater well-being for those surviving a cardiopulmonary arrest and discharged home. The use of an analytical conceptual model such as that proposed by Leidy (1994a) provides clarity to functional status and the four dimensions, thus enhancing the description of functional status.

Functional Status: Leidy's Theoretical Framework

According to Leidy (1994a) (Appendix A), all dimensions of functional status must be considered simultaneously in order that it be fully analyzed and understood. Individual elements of functional status may be evaluated and studied separately; however, this should be clarified through the appropriate use of terminology. The

following are definitions by Leidy that provide an analytical framework in which to evaluate functional status and the four dimensions that lie within functional status. For the purposes of this study, perceived functional capacity and physical functional performance was studied. The other concepts are listed so the reader fully understands all aspects of the framework.

Functional Capacity

Functional capacity is defined as one's maximum potential to perform those activities people do in the normal course of their lives to meet basic needs, fulfill usual roles, and maintain their health and well-being. The term refers to potential in any domain including physical, cognitive, psychological, social, spiritual, and sociodemographic. For the purpose of this study functional capacity was referred to as the perceived functional capacity variable as it is the perceived maximum potential of the individual.

Functional Performance

Leady (1994a) defined functional performance as any one of the domains of the physical, psychological, social, occupational or spiritual activities that people actually do in the normal course of their lives to meet basic needs, fulfill usual roles, and maintain their health and well-being. For the purpose of this study functional performance will be referred to as physical functional performance and it will be demonstrated how physical performance influences other domains within functional performance.

Functional Reserve

Functional reserve is the difference between capacity and performance, one's functional latency, or dormant abilities that can be called upon in time of perceived need.

Functional Capacity Utilization

This term refers to the extent to which functional potential is called upon in the selected level of performance.

Understanding each dimension and knowing that one dimension can influence the other dimensions has significance when trying to specify accurately the practice or study objectives, select the appropriate intervention protocol, and designate an outcome measure with the greatest likelihood of demonstrating effect (Leidy, 1994b). Leidy further stated that it is critical to understand each of these dimensions, as each is unique and fluid within the framework and that one could measure a single dimension with the understanding that it is written as such. As an example of how the dimensions influence each other, as functional capacity increases, exertion increases, performance approaches capacity, and reserve is diminished. Furthermore, Leidy summarized that as one aged or experienced chronic illness, functional status would change over time, making this framework applicable to the aging population. Under these circumstances, functional capacity could be limiting, functional reserve restricted, and functional performance likely to play a more prominent role in the perception of life quality.

The proper development and selection of outcome measures is critical to demonstrating treatment effects. For example, illness-related symptoms and performance indicators (e.g., activities of daily living [ADLs]) were often included in survey measures in which a total *functional status* score was calculated (Leidy 1994b). Leidy stated, however, that symptoms were an element of capacity (e.g., pain could hinder mobility, lead to reduced muscle function or joint flexibility, all of which restricted capacity and

might, but need not, influence performance). Leidy's work is useful in that it provided an analytical framework from which to work and accurately describes the functional status of patients no matter what disease process was under investigation.

Functional Status Post Cardiopulmonary Arrest

With these findings, along with the increase in survivors of cardiopulmonary arrest, health care providers will be facing a population with unique health care issues. Research has demonstrated an interest in functional status, but capturing the data is difficult and often times confusing due to the interchangeable use of *quality of life* and the inconsistent measurement or description of *functional status*.

The concept of quality of life after surviving a cardiopulmonary arrest has received much attention from several groups of researchers in the past decade. The focus of this descriptive study is to explain functional status in individuals who survive cardiopulmonary arrest. Many researchers have defined functional status as a multidimensional concept encircling issues of simple, everyday activity, such as self-care, to more specific measurements, such as neurological outcomes attempting to explain or measure functional status for the unique population being explored. This has lead to multiple measures that are distinct for each illness and population.

A major complicating factor for this study is that there are multiple measurements and definitions of functional status that researchers have used inconsistently in the literature. The lack of agreement results in problems in scientific communication, information retrieval, and comparison of findings from study to study and synthesis of the findings. It is important to study functional status because, as Leidy (1994b) stated, functional status is distinctive from quality of life. Functional status, like quality of life,

has multiple interpretations and measurements. Leidy suggested that functional status refers to the entire domain of functioning and defined it as a multidimensional concept characterizing one's ability to provide for the necessities of life; that is, those activities people do in the normal course of their lives to meet basic needs, fulfill usual roles, and maintain their health and well-being.

Minimal research was found describing functional status in the population surviving a cardiopulmonary arrest. Describing the dimensions of functional status in the survivor of a cardiopulmonary arrest can provide a robust description of functional status in this selected population and provide a clearer understanding of the concept so that is it might be used correctly and consistently within the literature. Secondly, healthcare providers will gain scientific insight through nursing research to design and evaluate outcomes appropriately in a unique population where functional status is a concern for a healthy life. This will further our knowledge regarding appropriate interventions to increase functional status. Functional status in the cardiopulmonary arrest survivor may have a dramatic and significant effect on their health and everyday performance therefore, it is important that healthcare providers accurately report, consistently measure and intervene appropriately.

Purpose and Aims

The purpose of this study is to examine functional status, specifically, perceived functional capacity and physical functional performance in adults who survive cardiopulmonary arrest within six months after discharge to home. The specific aims of the project are:

Aim 1

Describe perceived functional capacity, physical functional performance, mental health, symptom distress, and demographic variables in survivors of cardiopulmonary arrest after discharge to home.

Aim 2

To examine the relationship among perceived functional capacity, mental health, symptom distress and physical functional performance and demographic variables in the survivor of cardiopulmonary arrest after discharge to home.

Theoretical Definitions

Cardiopulmonary arrest is defined as documented ventricular fibrillation, ventricular tachycardia, or brady/asystole with concomitant loss of consciousness that was converted to a hemodynamically stable cardiac rhythm following cardiopulmonary resuscitation (CPR).

In-hospital cardiopulmonary arrest is defined as documented ventricular fibrillation, ventricular tachycardia, or bradycardia/asystole with concomitant loss of consciousness that occurred within the hospital to a patient and was converted to a hemodynamically stable cardiac rhythm following CPR.

Perceived Functional capacity is defined as one's maximum potential to perform those activities people do in the normal course of their lives to meet basic needs, fulfill

usual roles, and maintain their health and well-being. The term refers to potential in any domain including physical, cognitive, psychological, social, spiritual, and sociodemographic Leidy (1994a).

Physical Functional performance is actual physical performance activities that people actually do in the normal course of their lives to meet basic needs, fulfill usual roles, and maintain their health and well-being Leidy (1994a).

Symptom Distress is the self-report of the somatic, concentration, and affective discomfort presently being experienced by the patient.

Mental Health is the feelings representing the four major mental health dimensions: anxiety, depression, loss of behavioral/emotional control, and psychological well-being. They can range from distress through neutral to a sense of positive well-being.

CHAPTER 2

Review of Relevant Literature

The purpose of this chapter is to offer a historical perspective concerning functional status in the cardiopulmonary arrest survivor. Using the bibliographic databases MEDLINE, CINAHL, and PsycInfo from the period 1984 to 2004 revealed there is minimal research or literature on functional status in the cardiopulmonary arrest survivor. Key search words of cardiac arrest in combination with surviving a cardiac arrest, functional status and quality of life were used resulting in 11,710 articles, which required a refined search of key words resulting in 222 articles of which 49 were selected for relevance and interpretation within this study.

Articles on the topic of quality of life and functional status were found but very few on the population of cardiopulmonary arrest survivors. Dissertation work in 1984 and later published by Sauve (1995), assessed the long-term physical functioning and psychosocial adjustment in survivors of sudden cardiac death. Findings showed that despite significant decreases in physical functioning and reports of mild to moderately severe cognitive impairments, few sudden cardiac death survivors are severely psychologically distressed. Sauve (1995) found that illness severity is a strong predictor of physical functioning, however its contribution to psychological distress is indirect, acting largely through the aegis of poor physical functioning and loss of pre-arrest work status.

The interchangeable use of functional status with quality of life has lead to various interpretations when discussing outcomes related to functional status, therefore it is important to delineate clearly between the two concepts to allow clear interpretation of functional status; therefore a broad concept of quality of life will briefly be discussed as well as the varied interpretations of functional status and issues of measurement. Finally, the literature revealed that various outcomes were used as the sole measurement of one's functional status (e.g., neurological performance, ADLs) while the multiple definitions

and the lack of conceptual clarity resulted in multiple measures of functional status. There is a plethora of articles in the literature regarding functional status in various populations; however, it has only been analyzed conceptually in one nursing publication by Leidy in 1994. Nursing as a discipline, is striving toward evidence-based practice with a foundation built upon clarity of concepts, theories, and appropriate measurement techniques (Wang 2004) and Leidy's framework provides the clarity needed for this complex concept of functional status.

Quality of Life

In evaluating quality of life measures before and one year after admission to an intensive care unit, Konopad, Noseworthy, Johnston, Shustack, and Grace (1995) defined quality of life as level of activity, ADLs, perceived health, support, and outlook on life. One year quality of life questionnaires were completed on 293 patients. Relative to baseline, there was a significant decrease in the level of activity and ADLs at 12 months post discharge. Perceived health status significantly increased over the year for patients more than 75 years of age. Though their question was quality of life, the investigators seem to be measuring a dimension of functional status, level of activity and ADL's. In the assessment of quality of life outcomes, Testa and Simonson 1996(Appendix B) detailed where functioning was placed within the dimension of quality of life and health domain of physical activity, which could lead to a misinterpretation of functioning. In comparison to Leidy's framework, Testa and Simonson's placement of functioning, though correct in the fact that functioning is a dimension of quality of life, can lead one to conclude that quality of life determines one's level of functioning. Leidy's framework provides a clear definition to one's functional status and does not blend the concept of quality of life providing an accurate explanation to one's functional status.

There were many elements that made up quality of life according to Bond (1996) that included *essential subjective elements* recognized by self-evaluation: (a) satisfaction with life, (b) cognitive abilities to evaluate life, (c) presence of social, emotional,

physical, and mental health, by self-evaluation criteria, (d) happiness, and (e) psychological well-being. The *essential objective elements* evaluated by others included: (a) evaluation of subjective elements by another, (b) socioeconomic status, (c) functional status, and (d) housing. Bond discusses the subjective and objective elements to quality of life and list functional status as one of the objective elements. Interestingly, the same subjective elements that Bond list are those same elements contained within Leidy's framework. Bond separates the two, whereas Leidy combines these elements to make up the four dimensions of functional status providing a more clear and concise definition.

According to Meyboom-de Jong and Smith (1992), functional status has many aspects, including role activities, instrumental activities of daily living (IADL), basic activities of daily living (BADL), and at least three dimensions (i.e., physical, emotional, social) and stated functional status was a concept of health that, in turn, was an aspect of the quality of life. To summarize these findings, quality of life in many ways does seem to explain functional status, but caution should be considered when explaining one's functional status. Quality of life encompasses the concepts of physical, psychological, social and spiritual. These concepts in turn can be measured both subjectively and objectively, well-being in subjective terms and functional status in objective terms. Quality of life does not determine one's functional status nor does functional status determine one's quality of life.

Functional Capacity

Miranda (1994) evaluated the influence of CPR on the components of quality of life in 477 patients who had received CPR and 500 who had not. This study found that, after discharge from the hospital, patients who recovered from circulatory arrest after CPR found their capacity for resuming work diminished after discharge from the hospital. Also, they seemed to experience a postponed negative effect on their mental functioning, especially the functions connected with the awareness of their environment.

ADLs, specifically ADL scales, have been used as a synonym for physical function, performance, or functional status when realistically, ADL scales assess the basic capacity of persons to care for themselves, hence representing a narrow range of performance and do not truly represent all aspects of functional status (Applegate, Blass, & Williams, 1990). Appelgate, Blass and Williams (1990) further assert that ADL scales were usually arranged hierarchically from the most basic of human functions (e.g., using the toilet, eating) to somewhat higher functions (e.g., dressing, walking). Myers (1992) stated the accepted theoretical premise underlying the construction of ADL scales was that functional status was related to the ability to perform tasks of daily living.

Jette, Haley, and Phengsheng (2003) presented an empirical comparison of four functional outcome instruments used in a Post-Acute Care (PAC) setting with respect to their content, breadth of coverage, and measurement precision. The measurements included: (a) the Functional Independence Measure (FIMTM) for acute medical rehabilitation, (b) the Minimum Data Set (MDS) for skilled nursing and sub-acute rehabilitation programs, (c) the Outcome and Assessment Information Set for Home Health Care (OASIS), and (d) the Short Form-36 (SF-36) for ambulatory care programs using only the 10 items related to physical functioning (PF).

The internal consistency values of the four functional ability instruments were MDS = 0.97, OASIS = 0.99, $FIM^{TM} = 0.99$, and the PF-10 = 0.99. When all items were combined from the four functional ability instruments the internal consistency of the items were 0.85. Only five of the items within the existing instruments (7.2%) exceeded the goodness of fit values. Jette et al. (2003) felt it was acceptable to combine the items from each of the four functional outcome instruments into an overall functional ability scale for the purposes of directly comparing their range of functional content, breadth of coverage, and measurement precision. The results illustrated limitations in the range of content, breadth of coverage, and measurement precision in each outcome measurement.

None appeared well equipped to meet the challenge of monitoring quality and functional outcomes across settings where PAC was provided.

Summarized these studies selected various measurements to describe functional capacity, but have used terms such as functional ability, capacity of resuming work status or capacity to care for one's self. Based upon Leidy's (1994a) framework these results could clearly and consistently represent functional capacity, providing clarity to the outcome measure presented.

Functional Performance

The attribute of functional independence, using the FIMTM on admission and discharge to rehabilitation facilities, was used to determine and measure functional status in stroke patients (Nick et al., 1998). The FIMTM was the current standard outcome measure for rehabilitation services. The FIMTM is a measure of functional status on admission and discharge from a rehabilitation facility as assessed by various care providers (e.g., nurses, occupational therapists, physical therapists, speech psychologists). The FIM is an 18-item, 7-level scale of patient performance, where 1 represented total assistance and 7 represented independence for each of the subscales. The possible total score on the instrument ranged from 18, total dependence, to 126, highest level of independence. Using descriptive percentiles for comparing patients within the sample and across samples, the FIM™ admit score for these stroke patients, the 75th percentile, or 3rd quartile was 76, meaning among this facility's stroke patients, 75 percent had an admission value of 76 or less and only 25 percent had a score greater than 76. Overall at time of discharge 50 percent of the patients gained less than 1 point per item on the 18item FIMTM describing that most patients make incremental, rather than quantum, changes in their level of functioning.

In a study using neurological outcomes as a predictor of functional status, Dhar, Ostryzniuk, Roberts, and Bell (1996) described functional status determination retrospectively by the chart for pre-arrest and post-arrest status using the five category

Pittsburgh modification of the Glasgow Outcome score for cerebral performance category (CPC) and overall performance categories (OPC). Those overall performance categories included, OPC I – normal, OPC II – mild to moderate disability but functionally independent, OPC III – severe disability and functionally dependent, OPC IV – vegetative state, and OPC V – dead.

Dhar et al. (1996) found in this descriptive study that pre-arrest functional status of the study population was equally distributed between OPC I (n = 87), OPC II (n = 112), and OPC III (n = 86). No patients who were OPC IV pre-arrest were admitted to the intensive care unit. This study surmised that 50% of the OPC I patients admitted survived to hospital discharge and that the majority (75%) were functionally independent (i.e., OPC I, OPC II). Only 37% of the OPC II pre-arrest admissions survived to hospital discharge; however, seventy one percent of these survivors were OPC II when discharged. Only 10 admissions (12%) who were OPC III before arrest survived to hospital discharge and none were functionally independent. To summarize, most patients returned to their pre-arrest functional independence and 58% of hospital survivors were alive 2 years after discharge. However, Hsu, Madsen, and Callaham (1996) found that the CPC score, relied on as a measure of functional outcome in cardiac arrest, correlated poorly with subsequent subjective quality of life scores and with validated objective functional testing instruments and therefore, conclusions based on the CPC score from the Dhar et al. (1996) study were suspect.

These studies focused on one's actual performance based on neurological outcomes or performance of physical activity. Using Leidy's (1994a) framework, physical performance can be described and measured as the physical, psychological, social, occupational, and spiritual activities that people actually do in the normal course of their lives to meet basic needs, fulfill usual roles, and maintain their health and wellbeing.

Functional Reserve

LaPier (2003) studied functional status during immediate recovery after hospitalization for coronary artery disease. The attribute of physical endurance, the measurement of a timed walk test, and physiological findings (e.g., electrocardiogram, oxygen saturation, blood pressure, rating of perceived exertion) were used to determine functional status. In this study, measurements of functional status included results from the 6-minute walk test (6MWT), the Duke Activity Status Index (DASI), and the RAND 36-Item Health Survey (36-IHS).

The study determined that the ability to perform ADLs was strongly related to the self-reported quality of life in patients with coronary heart disease immediately after hospitalization. The results also indicated that total and physical functioning scores of quality of life and the DASI provide similar information. Furthermore, the study demonstrated that performance-based (6MWT) and self-reported (DASI, 36-IHS) assessments did not provide synonymous information regarding functional status in this patient population. Therefore, it is important to include both performance-based and self-report measures in studies examining patient functional status outcomes.

Graves et al. (1997) researched survivors of out-of-hospital cardiopulmonary arrest and determined their prognosis, longevity and functional status. The attribute of neurological outcome to determine functional status was discussed by using the five point cerebral performance category (CPC) classification scores. Graves et al. found that a large proportion of patients had CPC scores indicating functional problems when discharged, but these functional problems decreased one year later. The majority of cardiac arrest survivors returned to normal or near normal functional levels within a year and then continued to live for many years. Graves study demonstrates that the ability to recover from a cardiopulmonary arrest does indeed exist. Though the Grave's study used neurological outcome to describe functional status, using Leidy's framework of functional status in this study along with self-perception of energy expenditure and actual

energy expenditure with the NewLife Style 2000 Activity monitor will provide a clearer understanding of actual functional status in this population beginning the process of clarification, thus providing a more effective means of communicating this concept for scientific and clinical progress.

In a study to determine functional status and the correlates following coronary artery bypass graft (CABG) surgery in women, and being consistent with the role performance mode of the Roy Adaptation Model (RAM), functional status was studied by DiMattio and Tulman (2003) as the performance of activities associated with life roles (Fawcett & Tulman, 1996); the focal stimulus being the physiological insult associated with CABG surgery. The results of this study found that women experienced significant gains in functional status over 6 weeks, particularly between 2 and 4 weeks. They most frequently engaged in personal care and low-level household activities during the study period and most reported improvement in their overall functional status. None of the women completely recovered or regained baseline functional status by 6 weeks post-CABG.

Knowing one's abilities in a time of need is important to the individual's ability to adapt and overcome critical events. Previous studies mentioned measured one's physical reserve of physical ability when called upon in different ways and describing it by exercise tolerance or level activity after a critical event. Using Leidy's (1994a) framework of functional reserve, which is the difference between capacity and performance, one's functional latency, or dormant abilities that can be called upon in time of perceived need, can provide a more concise description of those abilities that can be called upon when needed.

Functional Capacity Utilization

Functional Capacity Utilization referred to the extent in which functional potential was called upon in the selected level of performance. It might be seen as the extent to which individuals realized their potential and is inversely related to reserve,

which would be the indirect measure of fatigue. As Functional Capacity Utilization increased, exertion increased, performance approached capacity, and reserve was diminished (Leidy, 1999).

Although Functional Capacity Utilization and performance were related, the former was expressed relative to capacity while the latter was expressed in absolute terms. Differences in Functional Capacity Utilization might be manifested symptomatically as could be demonstrated with variations in fatigue given the same level of performance; trained, untrained, and ill individuals would report different levels of fatigue as a consequence of differences in capacity utilization (Leidy, 1994a).

In a prospective, repeated-measures study, Barnason, Zimmerman, Anderson, Mohr-Burt, and Nieveen (2000) examined functional status outcomes among patients with CABG over time (i.e., at baseline; 3 months, 6 months, 12 months post surgery) and the impact of selected patient characteristics (i.e., age, sex, co-morbidities, cardiac rehabilitation participation) on functional outcomes. Functional status outcomes were measured utilizing the Medical Outcomes Study (MOS) Short Form 36 (SF-36) and Modified 7-Day Activity instruments.

Findings from this study demonstrated rebound of both physical and social aspects of functioning in the early post-hospitalization period (i.e., 3 months after surgery), validating the realized benefits of the cardiac intervention for some distinct areas of functioning. However, levels of vitality attained only modest levels indicating perceptions by patients that complete or maximum potential of vitality had not been attained even by 12 months after surgery (Barnason et al, 2000). Suggested examples of interventions to improve functional status might include symptom management (e.g., pain management, fatigue management), individualized cardiac rehabilitation, psychosocial support, and the use of technologies to assist patients in attaining optimum functional status and reducing CAD risk factors.

As noted, functional capacity utilization was "the extent to which capacity is called upon in the selected level of performance" (Leidy, 1994a, p. 199). Both functional reserve and functional capacity utilization add clarity to the understanding of functional status. However, there is no formula to calculate the difference between capacity and performance, or a reference available to judge high versus low reserve, but it is important to be aware of the difference between capacity and performance and address them while assessing individual functional status (Wang, 2004).

Varied Interpretations of Functional Status

Meyboom-de Jong and Smith (1992) stated functional status had many aspects including role activities, independent activities of daily living (IADL), basic activities of daily living (BADL), and at least three dimensions (i.e., physical, emotional, social). To determine where functional status was within the concept of quality of life, Appendix C cited four dimensions that are commonly referred to within the literature: (a) physical, (b) psychological, (c) social, and (d) spiritual with the indicators of QOL listed as Well-being (subjective) and Functional Status (objective). It was important to understand that functional status was an objective indicator of QOL and it alone did not determine one's QOL.

Health status, functional status, and QOL are three concepts often used interchangeably to refer to the same domain of health (Guyatt, Feeny, & Patrick, 1993). However, Leidy (1994a) stated that functional status was unique from QOL; that functional status, like QOL, had multiple interpretations and measurements. Leidy suggested that functional status referred to "the entire domain of functioning . . . [and defined it as] a multidimensional concept characterizing one's ability to provide for the necessities of life; that is, those activities people do in the normal course of their lives to meet basic needs, fulfill usual roles, and maintain their health and well-being" (p. 197).

The domain of functioning was not confined to physical functioning but also included psychological, social, and spiritual functioning. Although the domains were

similar to those identified in QOL, Leidy (1994b) emphasized that functional status was different because it was measured objectively. An example by Leidy suggested that spiritual functional status might be evidenced by church attendance or participation in prayer, which was different than the much broader spiritual domain of QOL

Issues of Measurement

The multiple definitions and the lack of conceptual clarity resulted in multiple measures of functional status. Early studies evaluating functional status were mainly conducted in primary care settings as a screening measure.

Functional status was evaluated by use of the Functional Status Questionnaire (FSQ) by Jette, Davies, Cleary, Calkins, Rubenstein, Fink et al., (1986), who conducted a reliability and validity test using the questionnaire in a Primary Care setting. The FSQ provided a comprehensive assessment in ambulatory patients of physical, psychological, social, and role function. The FSQ was designed to screen for disability and to monitor clinically meaningful change in function. Internal consistency reliabilities for the six FSQ scale scores ranged from 0.64 to 0.82.

Lapier (2003) assessing functional status during immediate recovery after hospitalization for coronary artery disease (CAD), using the 6-minute walk test (6MWT) with the self reports from the Duke Activity Status Index (DASI) and the SF 36-Item Health Survey (36-IHS). Results demonstrated that performance based (6MWT) and self-report (DASI, 36-IHS) assessments do not provide synonymous information regarding functional status in the CAD population. Therefore it is important to include both performance based and self-report measures in studies examining patient functional outcomes as the (6MWT) can not alone describe functional status.

Meyboom-de Jong and Smith (1992) found the BADL, IADL, and psychological function scores achieved the highest reliabilities. Work performance, social activity, and quality of interaction scores were less reliable. The quality of social interaction score was least reliable for participants 65 years of age and older; the reliability of other scale

scores did not decrease with advancing age. Though limited, it did provide the clinician the ability to highlight areas of potential functional limitation.

Blake and Vandiver (1986), conducted a study measuring the reliability and validity of a Ten-item measure of functional status, called the mini-DUHP, which is a subset of The Duke-UNC Health Profile (DUHP), a 63-item instrument that assessed four dimensions of functional status: symptom experiences, physical function, social function, and emotional function. On both administrations of the instrument to 71 subjects in a primary care setting, mini-DUHP scores were highly correlated with composite DUHP scores (r = .81; r = .84) and moderately correlated with each of the four functional dimension scores.

In 1990, Ware and Rand Corporation conducted an analysis of the SF-36 Health Survey, which was designed as a generic indicator of health status for use in population surveys and evaluative studies of health policy. The SF-36 included multi-item scales that measured the following eight dimensions: *physical functioning*, *role limitations due to physical health problems*, *bodily pain*, *social functioning*, *general mental health* covering psychological distress and well-being, *role limitations due to emotional problems*, *vitality* (i.e., energy, fatigue), and *general health perceptions*.

The alpha internal consistency had been reported from many studies and combining results from these studies, the median alpha reliability for all scales exceeded 0.80, except for the two-item social functioning (SF) scale (0.76). All scales appeared sufficiently reliable for comparing groups and the physical functioning (PF) scale appeared reliable enough for comparing individuals.

Content validity was also established for the SF-36 Survey by use of empirical approaches, including factor analytic tests of construct validity, criterion-based approaches, and numerous correlation studies. Content analysis revealed that the SF-36 includes eight of the health concepts most frequently represented in widely used health status measures. The SF-36 differed from most other measures in that it attempted to

present a wider range of levels for most of these concepts. Therefore, it would be an extremely important measurement assessment in determining an individual's functional status after surviving a cardiopulmonary arrest.

The physical functioning (PF) and mental health (MH) scales were relatively wholesome, being specific to medical or psychiatric disorders. The two role scales mostly reflected physical or mental conditions, but not exclusively. By design, the social functioning (SF) and vitality (VT) scales reflected both physical and mental conditions. The GH perceptions scale appeared to be most sensitive to physical health problems.

According to Haas (1999), the historical precedence for interpreting functional status only in the physical domain was evidenced by continued use of the Karnofsky scale. Karnofsky developed this tool to measure nursing workload. Haas went on to say that, although it was not designed as a quality of life measure, it was frequently used in this manner; actually what the instrument measured was physical functional status on a scale from 0-100 based on a person's ability to perform ADLs which provides minimal variability to the scale.

Although research focusing on functional status in various populations and settings seemed sporadic, difficulty in defining functional status and providing a conceptual framework had been the greatest obstacle. Several important variables related to functional status emerged from the preceding review of the literature. Factors contributing to the measure of functional status included ADL's, IADL, ability to fulfill usual roles, maintain their health and well-being, and the dormant abilities that could be called upon in time of perceived necessary (Leidy, 1994b).

As mentioned, studies have attempted to measure functional status but have not clearly captured the concept and have used quality of life interchangeably with functional status. Examples included evaluating neurological outcome to determine functional status by using the 5-point CPC classifications scores by Graves et al. (1997). Nick, Williams and Barker (1998) measured functional independence on admission and discharge to

rehabilitation facilities to determine and measure functional status. LaPier (2003) used physical endurance based upon physiological measurements to determine functional status post coronary artery bypass surgery.

Coyne and Allen (1998) presented an article on the assessment of functional status in patients with cardiac disease. They determined that the measurement of functional status lacked conceptual clarity, frequently focused on only one dimension of functioning, and overlooked the individuality of the patient. In addition, some measures of functional status had questionable sensitivity to capture change over time or the ability to discriminate between groups and lacked reports of reliability and validity testing.

The preceding literature review demonstrated gaps in functional status measurement and the use of an analytical conceptual model such as Leidy's (1994a) that clearly defined functional status and the four dimensions. Furthermore, given the prognostic importance of functional status measures, the results highlighted the importance of developing a reliable and efficient means of obtaining functional status as well as capturing the multidimensional aspect of functional status.

What is Known

According to Wang (2004), antecedents to functional status are, a human 'possesses ability' to perform activities necessary for daily life, there are 'normal expectations' regarding human activities and the necessities of human life can be realized through human activities. The consequences of functional status are that it is maintained and or impaired. If functional status is maintained, one could actively participate in his/her life. However, if functional status cannot be maintained, certain difficulties in activities of daily life will be experienced and may eventually lead to a limited level of functioning and a degree of disability (Wang, 2004).

Research Variables of Interest for this Study

There are few published studies on the functional status of cardiopulmonary arrest survivors. Results from previous studies examined quality of life or health status and

reported this as being functional status. This study evaluated functional status using Leidy's (1994a) framework, with selected variables, in cardiopulmonary arrest survivors discharged home and non-cardiac arrest, post myocardial infarction subjects actively engaged in cardiac rehabilitation as a comparison group.

Non-Cardiac Arrest, Post Myocardial Infarction Group

To assist in the description of functional status in the cardiac arrest group, a comparison group of post myocardial infarction subjects actively engaged in cardiac rehabilitation were included in the study. This group was selected for several reasons; surviving a cardiac arrest is low, with rates being 3-7 percent, so a larger sample size was needed for statistical analysis. Physiologically the myocardial infarction group is the closest comparable group to a cardiac arrest survivor as it is the intent of this study to examine and describe functional status. In both groups the heart was affected either by a lethal arrhythmia requiring cardiopulmonary resuscitation or a myocardial infarction affecting cardiac output, physical performance, mental status and role participation at home or at work, thus in both groups functional status was affected by the same organ. Therefore from a methodological standpoint it was reasonable to use post myocardial infarction survivors as a comparison group.

Perceived Functional Capacity

Perceived functional capacity represents one's maximum potential to perform activities that are done in the normal course of their lives to meet basic needs, fulfill usual roles and maintain their health and well being. One's capacity may be limited by their perception of the potential or fear that another cardiopulmonary arrest may occur.

Physical Functional Performance

Physical performance represents the actual physical performance of activities that are actually done in the normal course of their lives to meet basic needs, fulfill usual roles and maintain their health and well being.

Symptom Distress

Symptom distress is the degree of discomfort from a specific symptom being experienced. Understanding reported symptoms and interventions, e.g. pain, might affect other related symptoms such as insomnia, fatigue and appearance. Individuals who are having pain most likely are not sleeping, are tired and have little interest in taking care of their appearance (McCorkle 1987). When pain is decreased, sleep improves, they are less tired and physical performance improves. A change in symptoms, measured by a reliable and valid instrument, may alert healthcare providers to a change in self-care ability and physical performance.

Demographics

The relationship of age to functional status has been reported in previous studies. Alem, Waalewijin, Koster and Vos (2004) found older age was not significantly associated with impaired cognitive, physical, and psychosocial functioning, but a trend was observed toward worse physical functioning with advancing age. However, in assessing the functional status improvement in the elderly (aged 65+) following coronary artery bypass graft during the first two years, Barnett and Halpin (2003) found physical functional status increased 39.1% from baseline to one year and 2.1% from one to two years. Role functioning increased 42.7% at one year and slightly decreased by 2.1% from one to two years post surgery.

Gender has been reported as a factor in level of functioning status. Dimattio and Tulman (2003) assessing functional status, specifically in women after coronary artery bypass, found women experienced significant gains in functional status over 6 weeks, particularly between 2 and 4 weeks. Barnett and Halpin, (2003) reported from baseline to 1-year post coronary artery bypass in the elderly (age 65+), female patients nearly doubled the percent gain of men for both Physical Function (+59.3% vs. +33.9%, respectively) and Role Function (+62.0% vs. +37.8%, respectively). Physical Function

scores continued to increase from 1 to 2 years for women (+9.5) compared to men (+0.7%).

Ethnicity was reported as a possibility of poor outcome, low functional status and prognosis in out of hospital cardiac arrest (OHCA) survivors. Groeneneld, Heidenreich and Garber (2003) examined racial disparity in cardiac procedures and mortality among long-term survivors of cardiac arrest. In this study of Medicare beneficiaries who survived to hospital discharge for OHCA, black race was associated with a decreased likelihood of defibrillator implantation and other invasive procedures compared with white OHCA survivors, a difference that in part appeared to account for the poorer long-term prognosis for black OHCA survivors. This study highlights the importance of determining whether research evidence is being uniformly translated into clinical practice and identifying opportunities to improve care and functional status.

Mental Health

Reported in the literature on cardiopulmonary arrest survivors are those mental health concepts such as anxiety, depression and vitality. Miranda (1994), evaluating the quality of life after cardiopulmonary resuscitation, found that patients who have recovered from a circulatory arrest after CPR resuscitation find their capacity for resuming work diminished after discharge from the hospital, while they seem to experience a postponed negative effect on their mental functioning, especially functions connected with the awareness of their environment, relating to depression and anxiety.

Saner, Rodriguez, Kummer-Bangerter, Schuppel and Planta (2002) reporting on the quality of life in long-term survivors of out-of-hospital arrest, found that 49 out of the 50 patients who were interviewed, judged their life as worth living. Thirty-nine led a completely independent life without help from the outside.

Stiell, Nichol, Wells, Maio, Nesbitt, Blackburn and Spaite (2003) cite that there is generally a widely perceived impression that the quality of life and functional status of

survivors of cardiac arrest is poor. Consequently, there are concerns that aggressive community-wide approaches to improving the chain of survival may be futile.

In the Stiell et al (2003) study, health related quality of life after citizen CPR, found that patients who survive cardiac arrest generally survive at a very high functional level.

Patients who do survive seem to be very grateful and to enjoy a relatively unrestricted life putting to rest that patients who survive out-of-hospital cardiac arrest are severely disabled.

Summary

The most comprehensive measurement of functional status found in the review of the literature was the SF-36 Survey. Reliability of the SF-36 has been established. Estimates of score reliability for the SF-36 scales have been reported in 14 studies investigating various disease processes, social conditions, and random samplings of the population in both the United States and the United Kingdom. All reliability estimates exceeded accepted standards for measure used with group comparisons. For each scale, the median of the reliability coefficients across studies equaled or exceeded 0.80, with the exception of the SF Scale at 0.76. Only the PF scale consistently exceeded the 0.90 standard of reliability.

The SF-36 Measurement Model (Appendix D) represents the items, scales, and summary measures that have similar attributes to Leidy's conceptual model of functional status. Empirical referents are the link for the SF-36 and Leidy's conceptual framework. Wang (2004) states functional status can best be represented by actual activities performed in various aspects of life, which include but is not inclusive or exclusive, personal care, ambulation, household activity, recreational activity and community participation. Leidy's conceptual framework defines functional status as "one's ability to provide for the necessities of life and necessities include physical, psychological, social, and spiritual needs that are socially influenced and individually determined" (Leidy, 1994a, p.197). The SF-36 rather than being disease, condition or procedure specific,

measures physical and mental health, social and role functioning (ability to do normal work activities) and reflects the full range of health states capturing the four concepts: physical functioning, mental health, social and role function and general health thus making the SF-36 a comprehensive questionnaire to describe functional status use with this population using Leidy's conceptual framework.

Understanding the concept of functional status and the population of interest will guide the researcher to select the appropriate dimension of functional status, whether it is functional capacity, functional performance, functional reserve, functional capacity utilization, or a combination of these, thus selecting the most valid and reliable measurement in which to assess that dimension correctly and accurately.

CHAPTER 3

Methodology

This chapter contains a description of the study design, data collection methods, and data analytic approaches used in the investigation of functional status in individuals who survived a cardiopulmonary arrest and post myocardial infarction subjects with no cognitive impairment that were discharged home. Leidy's (1994a) concept definition of functional status served as the framework, the identification of study variables, and the research questions.

Research Design

A correlational, mixed method design with a convenience sample was used to investigate the functional status of individuals who survived a cardiopulmonary arrest without cognitive impairment and as a comparison, a group of non-cardiac arrest, myocardial infarction subjects actively engaged in cardiac rehabilitation were included. This study design was selected primarily because it allows for the examination of multiple variables and the relationship among these variables. Since the current scientific work related to functional status of patients surviving cardiopulmonary arrest is limited, the researcher determined that there was a need for descriptive data that could add to the body of knowledge and in addition, recovery following life-threatening illness could be associated with multiple patient and illness factors. Yet, there are severe gaps in knowledge about the direction and magnitude of these associations in functional status.

To implement this design strategy, data collection approaches were employed after approval by the Institutional Review Boards (IRBs) at the University of San Diego and the Cardiac Rehabilitation Center at a local facility:

- 1. Community announcements such as newspapers, Union Tribune and San Diego Weekly Reader were used to place advertisements to recruit potential participants as well as flyers placed in community venues. Participants were invited to telephone the researcher to determine eligibility and additional information was provided concerning the research study if participant was eligible and agreed to participate. If participant was willing to participate a place was determined at the convenience of the participant where voluntary consent was obtained and further instructions were given regarding study protocol.
- 2. Participants were given three structured questionnaires to complete. These instruments include the, Mini-Mental, SF-36 General Health Survey and the Symptom Distress Scale. These questionnaires were completed after the patient had volunteered to participate in the study and consented to the study.
- Participants were given an NL-2000 Activity Monitor to wear for seven days.
 Instructions were provided and a return demonstration from the participant required.
- Participants were asked three qualitative questions to enhance the quantitative findings: 1) What one significant thing has changed in your life since your event?
 What significant change in your lifestyle or physical activity has occurred since your event? 3) Since your event you have come in contact with several healthcare professionals, nurses, doctors and other healthcare personnel. What did you find to be the most helpful with these encounters and what changes would you recommend improving communication?

In general, this study was aimed to identify which selected medical and psychosocial factors (e.g., symptom distress, personal support) were more related to differences in survivor reports of their current physical functioning, mental health, and self-health perception. Secondly, the researcher compared participants self-report of physical functioning to physical performance and gleaned information gained from the qualitative interviews.

Sample

The population of interest was adults 40 years of age and older, male and female, who survived a cardiopulmonary arrest without cognitive deficits and were discharged home within 6 months of hospitalization. The non cardiac arrest group consisted of individuals actively engaged in cardiac rehabilitation post myocardial infarction.

Subjects were recruited using convenience sampling; a form of non-probability sampling because the subjects must consent to participate.

Criteria for inclusion in the sample included the following:

- 1. Patients who have experienced cardiac arrest necessitating external cardiopulmonary resuscitation, direct current cardioversion or both.
- 2. Patients who had a non-cardiac arrest, myocardial infarction, and were actively engaged in cardiac rehabilitation.
- 3. Adult patients age 40 years or older of either gender.
- 4. Alert and orientated with no cognitive impairment
- 5. Patients who could read and speak English.
- 6. Patients who reside within a 100-mile radius of the San Diego County Area.
- 7. Patients discharged from hospital within the past 12 months.

- Actively engaged in cardiac rehabilitation post myocardial infarction.
 Exclusion criteria for this sample included
- The existence of cognitive inability, delusional or psychological impairment has
 occurred which would prevent there ability to answer questions or operate the
 NL-2000 Activity monitor correctly.
- 2. Informed consent was not possible
- 3. Meets below minimum score based on age and education per Mini-Mental State Exam population norms (Table 1).

Subjects were invited by the investigator to participate in the study after the research plan had been approved.

Sample Recruitment

The approach for subject recruitment for this study was by public medium of various advertisement venues. After approval by the Institutional Review Board at the University of San Diego advertising strategies consisted of ads in the Union Tribune local newspaper that has 260, 629 readers in the central, east and south zones of the San Diego County. Advertisement ran twice to ensure saturation of county. Advertisement in the Weekly Reader with a readership of 797,500 for San Diego county for one week, radio announcement four times a day for one week on local AM station. Postings at local community centers and posting on and in the Near Death Experience website http://www.near-death.com and newsletter. After approval from Institutional Review Board at a local cardiac rehabilitation center and the University of San Diego's IRB, a comparison group was included of patients who had a myocardial infarction, non-cardiac arrest and were actively engaged in cardiac rehabilitation to add richness to the study.

Facilities for Data Collection

The data was collected by means of public announcements, primarily advertisements in the Union Tribune, Central Zone that consisted of a total population of 1.04 million, 789,372 adults with a readership of 317,065. Advertisement was also placed in the San Diego Weekly Reader, which consisted of 170,000 readers weekly and included areas from Oceanside, El Cajon, San Ysidro and La Jolla. Advertisements were published for one week each, Union Tribune being Thursday and Saturday, the Weekly Reader being Thursday. These advertising mediums were deemed the best to reach the population desired for the study. The readership for the Weekly reader in the 45+ years category is 43.2% and the Union Tribune Central Zone readership 35-55+ years category is 36%.

Operational Definition of Variables and Instrumentation

The instruments used in this study included three questionnaires, an activity monitor and three qualitative questions. The three questionnaires include the Mini-Mental State Examination, SF-36 General Health Survey, and the Symptom Distress Scale. The activity monitor used was the New-Life Style 2000 Activity Monitor (NL-2000).

Mini-Mental

The Mini Mental State Examination (MMSE) (Appendix G) is a widely used method for assessing cognitive mental status and for the purposes of this study was the initial instrument administered to determine if study participants had the cognitive ability to complete the remaining questionnaires and operate correctly the NL-2000 Activity Monitor. The evaluation of cognitive functioning is important in clinical settings because of the recognized high prevalence of cognitive impairment in medical patients. As a

clinical instrument, the MMSE has been used to detect impairment, follow the course of an illness, and monitor response to treatment. The MMSE has also been used as a research tool to screen for cognitive disorders in epidemiological studies and follow cognitive changes in clinical trials.

While the MMSE has limited specificity with respect to individual clinical syndromes, it represents a brief, standardized method by which to grade cognitive mental status (Folstein, Folstein and McHugh 1975). It assesses orientation, attention, immediate and short-term recall, language, and the ability to follow simple verbal and written commands. Furthermore, it provides a total score that places the individual on a scale of cognitive function.

Cognitive performance as measured by the MMSE varies within the population by age and educational level (Table 1). Crum, Anthony, Bassett and Folstein (1993), found there is an inverse relationship between MMSE scores and age, ranging from a median of 29 for those 18 to 24 years of age, to 25 for individuals 80 years of age and older. The median MMSE score is 29 for individuals with at least nine years of schooling, 26 for those with 5 to 8 years of schooling, and 22 for those with 0 to 4 years of schooling.

Table 1. Interpretation of Mini-mental State Score based on Age and Education

Interpretation of Mini-mental State Score (Maximun:30)

- A. Normal score: 24 or higher
- B. Educational and Age Norms
 - 1. Fourth Grade Education
 - a. Ages 18 to 69: Median MMSE Score 22-25
 - b. Ages 70 to 79: Median MMSE Score 21-22
 - c. Age over 79: Median MMSE Score 19-20
 - 2. Eight Grade Education
 - a. Ages 18 to 69: Median MMSE Score 26-27
 - b. Ages 70 to 79: Median MMSE Score 25
 - c. Age over 79: Median MMSE Score 23-25
 - 3. High School Education
 - a. Ages 18 to 69:Median MMSE Score 28-29
 - b. Ages 70 to 79: Median MMSE Score 27
 - c. Age over 79: Median MMSE Score 25-26
 - 4. College Education
 - a. Ages 18 to 69: Median MMSE Score 29
 - b. Ages 70 to 79: Median MMSE Score 28
 - c. Age over 79:median MMSE Score 27

The MMSE is reliable on a 24-hour or 28-day retest by single or multiple examiners. When the Mini-Mental Status was given twice, 24 hours apart by the same tester on both occasions, the Pearson correlation coefficient was 0.887 (Folstein et al. 1975).

SF-36 Health Survey

The SF-36 Health Survey (Appendix E) has been used effectively to document changes in health-related quality of life variables in patients with coronary artery disease after CABG surgery (Kiebzak, Pierson, Campbell, & Cook, 2003). For this study, the SF-36 Health Survey will be used to measure the dependent variables of self-perception of physical and mental health in survivors of cardiac arrest. This survey was developed by Ware, Kosinski, and Keller (1994) to determine how people felt about themselves, how

well people were able to do their usual activities, and how they rated their own health. The results from this study will be compared to functional status based upon Leidy's (1994b) framework to determine how surviving a cardiopulmonary arrest has affected their perception of physical and mental health.

This 36-item survey provides a direct method for assessing an individual's perception of their health. The SF-36 Health Survey is composed of eight health concept scales: Physical Functioning (PF), Role-Physical (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role-Emotional (RE), and Mental Health (MH). Each sub-scale measures either a physical and/or mental component of health. To score each of the individual scales, one adds the numbers circled by the respondent and sums the final item values. A higher score indicates a better health state. Physical health is measured by the PF, RP, BP, and GH scales, which when taken together comprise the Physical Component Scale (PCS). Mental health is measured with the VT, SF, RE, and MH scales, which together comprise the Mental Component Scale (MCS). However, in using Leidy's framework of functional status, each subscale was further analyzed to further explore the phenomenon in this population. As noted, there are multiple factors that influence one's functional status, therefore utilizing the raw PCS or MCS score does not clearly describe or evaluate functional status as this has been the case in previous studies that selecting one factor to determine or measure one's functional status is not accurate. The SF-36 Health Survey items are scored using a 3- to 6-point Likert scale. Seven yes or no items are also included in the survey, with a yes scored as one point and a no scored as two points.

Reliability of the SF-36 Health Survey has been established as estimates of score reliability for the SF-36 scales have been reported in 14 studies investigating various disease processes, social conditions, and random samplings of the population in both the United States and the United Kingdom. All reliability estimates exceeded accepted standards for measure used in-group comparisons. For each scale, the median of the reliability coefficients across studies equaled or exceeded 0.80, with the exception of the SF Scale, which was 0.76. Only the PF scale consistently exceeded the 0.90 standard of reliability.

Content validity was also established for the SF-36 Health Survey by use of empirical approaches, including factor analytic tests of construct validity, criterion-based approaches, and numerous correlation studies. Content analysis revealed that the SF-36 included eight of the health concepts most frequently represented in widely used health status measures. The SF-36 differed from most other measures in that it attempted to present a wider range of levels for most of these concepts. Therefore, the Sf-36 would be an extremely important measurement assessment in determining an individual's functional status after surviving a cardiopulmonary arrest.

Perceived Functional Capacity

Perceived Functional capacity is one's maximum potential to perform those activities people do in the normal course of their lives to meet basic needs, fulfill usual roles, and maintain their health and well-being. The term refers to potential in any domain including physical, cognitive, psychological, social, spiritual, and sociodemographic (Leidy 1994). This variable was measured with the subscales of the

SF-36: Physical Functioning (PF), Role-Physical (RP), General Health (GH) and Vitality (VT).

Physical Functioning (PF)

The 10-items in the PF scale ask respondents to indicate the extent to which their health limits them in performing physical activities.

Role-Physical (RP)

The 4-items in the RP scale ask respondents to what degree their physical health limits them in the kind of work or other usual activities they perform, causes them decrease the amount of time they spend on work or other usual activities, and causes difficulty in performing work or other usual activities.

General Health (GH)

The five items in the General Health scale obtain respondents' assessments of their current health status overall, susceptibility to illness, and their expectations for health in the future. Scores from this scale provide a good summary of health status overall, and reflect the impact of specific symptoms and other health states experienced but not captured explicitly by other scales.

Vitality (VT)

The four items in the vitality scale capture changes in subjective well-being by asking respondents to indicate how frequently they experience feelings of energy and fatigue.

Physical Functional Performance

Actual physical performance are activities that people actually do in the normal course of their lives to meet basic needs, fulfill usual roles, and maintain their health and

well-being. This variable was measured by the energy expenditure for seven days recorded as energy expenditure with the New-Life Style 2000 Activity Monitor.

Electronic pedometers have gained widespread acceptance among physical activity researchers over the past decade. Researchers have commonly used them in physical interventions, especially those that use walking as the primary mode (Bassett & Strath, 2002). In addition, pedometers or activity monitors, such as the New-Life Style 2000, are often used as an adjunct to physical activity questionnaires since researchers recognize the advantage to having a simple, accurate, and objective measure of energy expenditure (Bassett & Strath 2002; Tudor-Locke, Williams, Reis, & Pluto, 2002).

In this study, the participants wore the New-Life Style 2000 Activity Monitor using a belt clip. This device provided the users with an accurate estimate of the calories burned throughout the day. It measured vertical acceleration (i.e., up and down motion) and total caloric expenditure (i.e., the calories one's body burns to keep functioning properly plus the calories one expends through exercise or activity). When positioned correctly on the hip, the New-Life Style 2000 Activity Monitor recorded a step each time the hip moved up and down. Proper placement does affect reliability so subjects were educated on the proper placement of the device and a return demonstration was required to ensure understanding of how to properly use the device. The activity monitor also measured activities one did throughout the day in addition to walking (e.g., bending to tie one's shoes, going up and down stairs). The individual input their age, gender, height, and weight, and the monitor determined their basal metabolic rate (BMR), providing an estimate of caloric expenditure and the intensity of one's activity; the higher the intensity, the more calories the unit registered. A small notebook was provided to allow the

participants, if desired, to document their daily energy expenditure based upon the New-Life Style 2000 Activity Monitor, but it was not necessary for the participants to record daily readings as the device has a seven day memory recall. The notebook was a recommendation from a pilot study conducted on seven participants and it was seen as a reminder to place the device on daily.

Schneider, Crouter, Lukajic and Bassett (2003) demonstrated the reliability of several pedometers including the NL-2000 in a study, where a total of 10 pedometers were assessed for accuracy and reliability. The results showed that the Kenz Lifecorder (KZ), New Lifestyles NL-2000 (NL), and the Yamax Digi-Walker SW-701 (DW) were the most accurate in counting steps, displaying values that were within \pm 3 % of the actual steps taken, 95% of the time. The reliability with a single model (Cronbach's alpha) was > 0.80 for all pedometers and the intramodel reliability was exceptionally high > 0.90.

Pedometers correlate strongly (median r=0.86) with different accelerometers depending on the specific instruments used, monitoring frame and conditions implemented, and the manner in which the outputs are expressed (Tudor-Locke, Williams, Reis and Pluto 2002). Pedometers also correlate strongly (median r=0.82) with time in observed activity and moderately with different measures of energy expenditure (median r=0.68). The relationship between pedometer outputs and energy expenditure is complicated by the use of many different direct and indirect measures of energy expenditures and population samples. The NL-2000 Activity monitor has incorporated into the device self-calculation for energy expenditure based upon age, height, weight and steps.

Symptom Distress

Self-reports are defined as the somatic, concentration and affective discomfort presently being experienced by the patient as measured by the Symptom Distress Scale. Degree of distress was measured on a five point bipolar scale, with 1 designating the least amount of stress or no distress for a specific symptom to 5 designating extreme distress. The range of possible scores was from 13 to 65.

McCorkle and Young (1978), in an effort to identify the concerns of patients receiving chemotherapy treatments, developed the Symptom Distress Scale (SDS; Appendix F). SDS is a general indicator of symptoms experienced by patients with cancer. It measured the occurrence of specific symptoms and provided an overall score of symptom distress. The instrument measured changes in symptom distress within an individual over time (Hinds, Quargnenti, & Wentz, 1992; McCorkle, 1987). SDS is a 13-item, Likert-type self-report scale that measures vomiting, nausea, pain, anorexia, sleep, fatigue, bowel elimination, breathing, coughing, and concentration. Patients rate specific symptoms on a scale from 1 to 5, with higher ratings indicative of more symptom distress. Total scores range from 13-65, and the scale takes 5 to 10 minutes to complete (Schinder, Prince-Paul, Allen, Silverman, & Talaba, 2004).

McCorkle (1987) found a correlation of .90 between SDS score and scores on the Ware et al. (1994) Health Perception questionnaire demonstrated convergent validity of the tool. The SDS discriminates between survivors of myocardial infarction and patients with cancer (McCorkle & Quint-Benoliel, 1983), as well as between patients with home care and with healthy controls. The reliability (coefficient alpha) ranged from 0.79-0.89 in numerous samples of adult patients with cancer (McCorkle 1987).

Demographics

(See appendix H for Demographic Questionnaire)

Mental Health

Mental health was defined as self-reports of affective mood state on a bipolar scale from distress through neutral to a sense of positive well being as measured by selected subscales of the SF-36 for this study: Social Functioning (SF), Role-Emotional (RE), Mental Health (MH), and Vitality (VT).

Social Functioning (SF)

The two items in the Social Functioning scale ask respondents about the impact of either physical health or emotional problems on normal or usual social activities.

Respondents were asked to indicate limitations in social function due to specifically to health; this minimized variation in scores that may be attributable to non-health related factors.

Role Emotional (RE)

The three items in the Role-Emotional scale asked respondents to what degree emotional problems have caused them to accomplish less in their work or other usual activities, cut down on the amount of time spent on work or other usual activities, and perform work or other activities less carefully. As with the Role-Physical scale, the items here refer both to work and "other regular daily activities," and thus are also applicable to many different roles in life.

Mental Health (MH)

The five items in the Mental Health scale asked respondents to indicate how frequently they experienced feelings representing the four major mental health dimensions: anxiety, depression, loss of behavioral/emotional control, and psychological well being.

Vitality (VT)

The four items in the vitality scale captured changes in subjective well-being by asking respondents to indicate how frequently they experienced feelings of energy and fatigue.

Data Collection Procedures

Institutional Review Board applications were submitted to the University of San Diego and after approval, advertisements were placed in the Union Tribune and San Diego Weekly Reader as well as community venues for recruitment of potential participants. IRB approval was also completed for the cardiac rehabilitation center from a local facility in San Diego for the non-cardiac arrest, post myocardial infarction subjects. Once approved, the exercise physiologist at the cardiac rehabilitation center was contacted, briefed on the study and advertisements were provided to the center for voluntary participants. Voluntary participants for both the cardiac arrest group and the non-cardiac arrest group contacted via phone; the primary researcher to determine if they meet eligibility. If the participant meet eligibility, a brief description of the study was given to the potential participant and if willing to participate in this seven-day study, the primary researcher set a meeting at the participant's convenience. At the meeting, a detailed explanation of the study was conducted and, if the participant remained willing to voluntarily participate, informed consent was obtained.

Order of Administration of Measures

The subjects completed the Mini-Mental, then the demographics questionnaire.

Administration order of the instruments was important to demonstrate if they had the cognitive ability to complete further requirements of the study. They were instructed on how to wear the New-Life Style 2000 Activity Monitor and how to record daily energy

expenditure in a notebook. Subjects were instructed to record in the notebook the daily energy expenditure displayed on the face of the activity monitor at the end of each day. The device itself had a seven day recall, but having the subject record the number daily was a reminder to wear the monitor each day upon rising, this was noted from a pilot study previously conducted using the same device. To ensure understanding, the subjects did a return demonstration using the NL-2000 Activity monitor to ensure proper wearing and placement of the device. At the end of 7 days, the participants completed the SF-36 Health Survey, Symptom Distress Scale and the three qualitative questions.

Data Collection and Recording

The initial data was collected at the designated site per participant's convenience, one subject at a time. Informed consent took about 10 minutes to obtain. The Mini Mental State Exam was given first to ensure participants could complete remaining questionnaires and operate the NL-2000 Activity Monitor. A demographics questionnaire was completed and the New-Life Style 2000 (NL-2000) was explained and the subject completed a return demonstration to show understanding in the use of the device, which subjects completed in approximately 30 minutes. This time was consistent with the pilot study of seven subjects between the ages of 50 and 82 years of age, assessing the time necessary to become familiar with the device. An instruction booklet was also provided to the subjects for future reference. The SF-36 General Health Survey and Symptom Distress questionnaires were given to each subject and asked to complete and return in seven days when the readings from the NL-2000 were obtained. A location was decided at the subject's convenience when and where the final meeting would take place.

All subjects decided not to record their daily energy expenditure in the notebooks as they felt that the device already recorded what was needed and writing it down was redundant. At the end of seven days, the readings from the NL-2000 were collected and the researcher reviewed the SF-36 and Symptom Distress Questionnaires to ensure all questions were completed. The subjects stated that the questionnaires were easy to read and took approximately fifteen minutes each to complete.

The three qualitative questions were decided after the final meeting took place with the cardiac arrest group; therefore follow-up telephone calls were required to obtain the information from this group. The subjects were happy to answer further questions related to the study. The non-cardiac arrest group followed the same procedure as the cardiac arrest group with the exception they were told at the initial meeting that three qualitative questions would be asked of them at the final meeting.

Data Processing and Analysis

Descriptive statistics were used to describe the sample and the study variables. Spearman's Rho correlation coefficients were used to calculate the relationship between study variables. The SPSS program for Windows was used for data analysis as well as the scoring software for the SF-36. Specific descriptions for aims and variables were:

Describe perceived functional capacity, physical functional performance, mental health, symptom distress, and demographic factors in survivors of cardiopulmonary arrest after discharge home. The Physical component summary score (PCS) and the subscales of the SF-36 measured perceived functional capacity: physical functioning (PF), role-physical (RP), general health (GH) and vitality (VT). The variable mental health was measured by the mental component summary score (MCS) and the subscales of the SF-36: social functioning (SF), role emotional (RE), mental health (MH), general health (GH) and vitality (VT). The variable physical functional performance was measured by the energy expenditure, average number of daily steps taken, calculated by the New-Life Style 2000 Activity Monitor. The Symptom Distress Scale measured the variable symptom distress. Descriptive statistics was used to describe these variables and demographics using SPSS 11.5 program.

Aim 2

To examine the relationship among perceived functional capacity, mental health, symptom distress and physical functional performance in the survivor of cardiopulmonary arrest after discharge to home. The Physical component summary (PCS) score and the subscales of the SF-36 measured perceived functional capacity:

physical functioning (PF), role-physical (RP), general health (GH) and vitality (VT). The variable mental health was measured by the mental component summary score (MCS) and the subscales of the SF-36: social functioning (SF), role emotional (RE), mental health (MH), general health (GH) and vitality (VT). The variable physical functional performance was measured by the energy expenditure calculated by the New-Life Style 2000 Activity Monitor. Symptom Distress was measured and scored using the Symptom Distress Scale. The statistics used to describe the relationship among these variables was correlation based on Spearman's Rho correlation and regression analysis.

Limitations of the Study

Due to the small sample size and homogeneity of patients, the ability to demonstrate a relationship between admission functional status and post cardiopulmonary arrest survival may not be conclusive. There was no measurement of long-term outcomes on functional status on the survivors as this study was limited to 7 days per subject. However, a comparison group of non-cardiac arrest, myocardial infarction subjects was included to help explain the phenomenon in the cardiac arrest group.

The second limitation of this study was the use of structured questionnaires to collect data on several study variables. Even though every effort was made to utilize instruments that have undergone extensive testing for reliability and validity, it is not possible to ascertain to what extent the subjects understood the intent of the questions or chose to answer the questions in an honest and thoughtful manner. To minimize this potential for response bias, the subjects were given verbal instructions as to the intent of each questionnaire.

The third limitation of this study was the possibility that participants would not record their daily energy expenditure or would have difficulty operating the device. To manage this, the researcher assisted the participant in setting up the monitor for initial use and had the participant provide a return demonstration of proper placement of the device when wearing. There was no difficulty noted in wearing the device and recording the daily reading was not a limitation as the device had a seven-day memory so all data was stored and writing down the daily readings was not an issue.

A fourth limitation to this study was obtaining IRB approval in local facilities due to HIPPA regulations and the access of patient information and databases thus limiting the total number of subjects to those who responded to the advertisements. However, the recruitment for this study was higher over the three-month period compared to previous studies conducted in hospital settings. Previous studies averaged one subject per month as compared to this study having fifteen subjects over a three-month period.

Subjects' Risks and Benefits

Potential risks. Minimal risk or discomforts were anticipated related to a subject's participation in this study. Risks or discomforts beyond those risks associated with any underlying medical condition that they might feel or associated with standard health care received during the course of their participation were felt to be no greater than the *normal* risks of day-to-day life. However, if during the interview the participants became tired, every effort was made to provide opportunities for participants to rest, if desired. If in asking questions related to mental or physical health the participant experienced emotions of distress or sadness, appropriate support was provided and, if needed, referral to a mental health professional (e.g., San Diego County Mental Health Hotline) was done.

None of the subjects experienced any emotions of distress or sadness, on the contrary they were happy to participate and found participating in the study "a fun thing to do." Given the potential benefits for enhancing the health of cardiopulmonary arrest survivors resulting from this study, the potential benefits outweighed the potential risks involved in this study.

Risk management. Prior to sampling, written approval of the study plan was obtained from the University of San Diego's Human Subjects Committee and the Institutional Review Board for Sharp Health Care System. Each subject was informed of his/her right to withdraw from the study at any time without consequences. Anonymity was maintained by assigning code numbers to subjects. The researcher kept all confidential information in a locked file cabinet. The researcher alone had access to the code numbers and files. The files were destroyed when the analysis was completed.

Potential benefits. Functional status is extremely important to the daily activity of individuals who survive cardiopulmonary arrest. Assessing one's energy expenditure and comparing questionnaire responses to energy expended could bring unrecognized positive self-perceptions to mind and reinforce them, which in turn, could help promote a feeling of well-being in the participants. Furthermore, identification of negative self-perceptions related to items pertaining to perception of health and energy expenditure may serve as an impetus to begin an exercise regimen.

Expense to subjects. There was no expense to the subjects; the New-Life Style 2000 Activity Monitor and notepad for documentation of energy expenditure were provided. At the completion of the study, subjects were given the option of keeping the

NL-2000 Activity Monitor for there own personal use as a gift and each was given a card with \$25 compensation for their time.

CHAPTER 4

Results

Sample

Twenty subjects were recruited from the San Diego County area from February 17th, 2005 to May 5th, 2005. The total respondents to the advertisements for this study was 20 with an attrition rate of 25% resulting in a final sample size of 15, eight cardiac arrest survivors and seven non-cardiac arrest, myocardial infarction patients. Subjects were excluded due to various reasons, as outlined in Table 2.

Table 2

Reason for Subject Exclusion

Number of Subjects	Reason for exclusion		
1	Did not meet age criteria of at least 40 years of age, 28		
1	Did not understand the meaning of cardiac arrest		
2	Subjects had experienced "panic attacks" not a cardiac arrest		
1	Did not feel they could adequately participate due to up coming vacation		

The age of the subjects ranged from 43 to 84 years old with a mean age of 62.8 years (SD \pm 13.07). Over half (53.3%) were between the ages of 40 and 65 years. The majority of subjects were married (73.3%), all had a minimum of a high school diploma, and 73.3% had some college education or higher. Eighty percent lived in a private residence and were male white non-Hispanic. Sixty percent of the subjects had no prior history of cardiac disease (Table 3).

To determine cognitive ability and ensure subjects were able to read and understand the questionnaires, the Mini-Mental State Exam (MMSE) was administered to subjects prior to the study. The standard MMSE score varies within the population based on age and educational level. All fifteen participants scored within the median MMSE score based on their age and educational level (range 27-29, maximum possible 30) demonstrating no cognitive impairment.

Data were collected over a one-week period, consistent with the procedures outlined in Chapter 3. Additionally, to make the study more robust, three qualitative questions were asked of the subjects in an effort to explain the phenomenon from the participants' perspective and provide greater meaning to the quantitative findings. As stated by Shepard, Orsi, Mahon and Carroll, (2002) "Coupling qualitative methods with quantitative methods can illuminate phenomena that cannot be captured using a singular approach." The three qualitative questions were 1). What one significant thing has changed in your life since your event? 2). What significant change in your lifestyle or physical activity has occurred since your event? 3). Since your event you have come in contact with several healthcare professionals, nurses, doctors and other health care personnel. What did you find to be the most helpful with these encounters and what changes would you recommend in improving communication?

To evaluate the accuracy of data entered into the software program, frequencies were run first to look for outliers. Of the 1,110 items of data entered in the demographic file and the four data collection files, two incorrectly keyed items were noted and corrected, (e.g., the number was incorrectly keyed as three for a scale with a range of 1-2).

Table 3 Subject Demographics

		Number	Percent
Age (Mean)		62.87	SD ± 13.07
Gender	Male	12	(80%)
	Female	3	(20%)
Race	White	12	(80%)
	Hispanic	1	(6.7%)
	Other	2	(13.3%)
Marital Status	Married	11	(72%)
	Single	2	(14%)
	Widowed	2	(14%)
Education	High School Graduate	4	(27%)
	Some College	7	(47%)
	College Graduate	3	(20%)
	Post Graduate	1	(6%)
Living Arrangements	Private Home	12	(80%)
	Apartment	3	(20%)
Smoke	Yes	1	(6.7%)
	No	14	(93.3%)
Arrhythmia at time of cardiac arrest (8)	Ventricular Fibrillation	1	(6.7%)
(No Non-Cardiac arrest patients experienced arrhythmia's)	Bradycardia	2	(13.3%)
	Ventricular Tachycardia	1	(6.7%)
	Other (SVT, Tachy arrhythmia)	4	(26.7%)
Arrhythmia at time of Myocardial	None	6	(40%)
Infarction (MI)	Other	1	(C 7 0/)
	Other	1	(6.7%)
History cardiac disease	Coronary Artery Disease (CAD)	4	(26%)
	MI	1	(7%)
	CAD and MI	1	(7%)
	None	9	(60%)
History of Congestive Heart Failure	Yes	2	(13.3%)
	No	13	(86.7%)
NYHA	Ш	1	(6.7%)
	IV	2	(13.3%)
	None	12	(80%)
Diagnosis	Cardiac Arrest	8	(53.3%)
	Myocardial Infarction	7	(46.7%)

Calculation of body mass index (BMI) was completed on the participants to explain physical health of the study sample. Mean weight was not significantly higher for the cardiac arrest patient's but body mass index was less (t = 1.714) (p > 0.05) when compared to the non-cardiac arrest group where mean weight was not significantly lower and body mass index was higher (t = -.726) (p > 0.05) (Table 4).

Table 4
Weight and Body Mass Index for Study Sample

	GROUP	N	Mean	Std. Deviation
WT	CA	8	199	32
	MI	7	170	32
BMI	CA	8	27.9	5.2
	MI	7	29.9	5.2

Mean wt higher for CA patient's but BMI less and mean wt lower for MI patient's but BMI higher (p>.05) (CA= Cardiac Arrest; MI= Myocardial Infarction)

The average steps taken, a measure of physical performance was recorded for seven days using the New Life-Style 2000 Activity Monitor. Results are presented in Table 5. No significant difference was noted between the cardiac arrest and non-cardiac arrest groups for average number of steps taken, indicating the activity levels were equal for both groups and lower than recommended daily steps (t = -.684) (p > 0.05)

Table 5

Average daily steps (n=15)

	GROUP	N	Mean	Std. Deviation
Avg daily Steps	CA	8	4392	3469
	MI	7	5819	4602

Recommended daily steps per US Surgeon General 10,000 daily but many who work white-collar jobs only reach 3,000 daily. (CA= Cardiac Arrest; MI= Myocardial Infarction)

Instrument Reliability and Validity

Because the instruments used in this study had not been used much in cardiac arrest survivors, reliabilities and validity were conducted and compared to reported data. The Physical Component Summary Scale (PCS) of the SF-36, which describes physical health, consist of four subscales, physical performance (PF), role perception (RP), general health (GH) and bodily pain (BP). The Mental Component Summary Scale (MCS) of the SF-36, which describes Mental Health, consist of four subscales, vitality (VT), social functioning (SF), role-emotional (RE) and mental health (MH). Bodily pain (BP) and vitality (VT) maybe used interchangeably and are found to be reliable in both summary scales (Ware, 1994). Perceived functional capacity was measured using PCS, substituting bodily pain with vitality. Internal consistency reliability for perceived functional capacity/physical component was .80 in this study

Mental health was measured using the MCS. Internal consistency reliability for mental health was .88 in this study. Symptom Distress was measured using the Symptom Distress Scale. Internal reliability was higher at .90 than previously reported with a

population discharged from the hospital within six months. Synopsis of instrument reliabilities can be found in Table 6.

Table 6

Instrument Reliability in Study Population

Instrument	Measure	Reported α	α for present study
SF-36:			
PCS	Perceived Functional Capacity/Physical Component	.89	.80
MCS	Mental Health/Mental Component	.84	.88
SDS	Symptom Distress MI patients	.75	.90

In demonstrating strength of explanation of the physical component and mental components of the SF-36 subscales, Ware, Kosinski, Bayliss, McHorney, Rogers & Raczek (1995) showed that the PCS, with the subscales measuring perceived functional capacity (PF, RP, BP, and GH), correlated strongly with the Medical Outcome Studies (r=.56 to.90) and MCS with the subscales measuring mental health (VT, SF, RE, and MH) had a moderate to strong correlation with the Medical Outcome Studies (r=.27 to .92).

Normative data means and standard deviations for perceived functional capacity (PCS), mental health (MCS), and Symptom Distress Scale are presented in Tables, 7, 8 and 9 respectively. Overall findings were not significant when compared to the general population with heart disease when comparing PCS scores (p > .05) or MCS scores (p > .05) indicating that the sample was consistent with the normal population Symptom distress did not differ significantly between this sample and a sample discharged six months from the hospital (p = .386) (McCorkle, 1984).

Table 7

Normative Data Means and SD Perceived Functional Capacity (PCS Score))

Mean	SD	F	Р
39.36	11.31		
39.84	11.61	.032	.861
	39.36	39.36 11.31	39.36 11.31

Table 8

Normative Data Means and SD Mental Health (MCS Score)

	Mean	SD	F	Р
Heart Disease (N=184)	48.84	11.44		
Study Sample (N=15)	44.18	13.28	.163	.693
Study Sumple (N=10)	0	10.20		.000

Table 9

Normative Data Means and SD Symptom Distress

	Mean	SD	F	Р
6 months after discharge (N=17)	22.2	7.1		
Study Sample (N=15)	24	7.78	.995	.337

(Note the higher the score the more symptom distress) Range 13-65

Data Analysis

Spearman rho (Y) was used to evaluate the relation between variables in the cardiac arrest group's perceived functional capacity, which was defined as one's maximum potential to perform those activities people do in the normal course of their lives to meet basic needs, fulfill usual roles, and maintain their health and well-being (Leidy 1994). Correlations were performed on the physical component summary score (PCS) and the mental component summary score (MCS) with age, gender, body mass index, length of stay in hospital, average number of daily steps and symptom distress.

Correlations were performed on perceived functional capacity, which consist of the four subscales (PF, RP, GH, VT), which make up the PCS score with age, gender, body mass index, length of stay in hospital, average number of daily steps and symptom distress.

This same procedure was followed for mental health in the cardiac arrest group. Mental health was previously defined as self-reports of an affective mood state on a bipolar scale from distress through neutral to a sense of positive well-being. Correlations were performed on mental health, which consist of the four subscales (SF, RE, MH, VT) which make up the MCS score with age, gender, body mass index, length of stay in hospital, average number of daily steps and symptom distress. The same correlation procedures were performed on the non-cardiac arrest group.

In the cardiac arrest group correlations were performed on the physical component summary score (PCS) and the mental component summary score (MCS) with age, gender, body mass index, length of stay in hospital, average number of daily steps and symptom distress. There were no significant findings (Table 10), therefore further exploration of the data using the subscales of the PCS and MCS were conducted to help explain the phenomenon of functioning among cardiac arrest survivors.

Spearman's Pho Correlation Coefficients Cardiae Arrest Crown PCS and MCS

Table 10

Spe	Spearman's Rho Correlation Coefficients Cardiac Arrest Group PCS and MCS									
Variable	Age	Gender	Stay	ВМІ	Steps	SDS	PCS	MCS		
Age	1.000	.289	658	164	.098	.356	098	317		
Gender		1.000	.058	.232	507	.113	507	.507		
Stay			1.000	.420	.099	.267	334	.136		
ВМІ				1.000	086	191	135	.184		
Steps					1.000	.144	.452	143		
SDS						1.000	659	539		
PCS							1.000	.238		
MCS								1.000		

BMI=Body Mass Index, Steps=Average number of daily steps, SDS= Total Symptom Distress Score, PCS= Physical Component Summary, MCS= Mental Component Summary

In the cardiac arrest group for perceived functional capacity, there was as a negative correlation between symptom distress with physical functioning (r = -.729, p < 0.05), general health (p = 0-.910, p < 0.05) and vitality (r = 0-.849, p < 0.05). These data suggest that increases in symptom distress are associated with decreases in physical activity, perception of health status and energy levels. There was a positive correlation between physical functioning and role perception (r = .768, p < 0.05) and general health (r = .778, p < 0.05), (Table 11).

Table 11

Spearman's Rho Correlation Coefficients Cardiac Arrest Group (Perceived Functional Caracity)

Ca	ipacity)									
Variable	Age	Gender	Stay	ВМІ	Steps	SDS	PF	RP	GH	VT
Age	1.000	.289	658	164	.098	.356	282	383	512	222
Gender		1.000	.058	.232	507	.113	510	443	169	.057
Stay			1.000	.420	.099	.267	168	024	.000	325
ВМІ				1.000	086	191	.031	450	.123	.118
Steps					1.000	.144	.479	.452	.095	229
SDS						1.000	729*	384	910*	849*
PF							1.000	.768*	.778*	.665
RP								1.000	.546	.497
GH									1.000	.687
VT										1.000

BMI=Body Mass Index, Avg=Average number of daily steps, SDS= Total Symptom Distress Score, PF=Physical Functioning, RP= Role Perception, GH=General Health, VT= Vitality *p=<0.05

This finding suggests that ones perception of life roles and health status are a function of physical activity. For mental health there was as a negative correlation between symptom distress and vitality (r = -.849, p < 0.05) and social functioning (r = -.790, p < 0.05). This finding suggests that ones perception of mental health depends of available energy, which also impacts participation in social activities. Vitality was positively correlated with role emotion (r = .857, p < 0.05). This finding suggests that

sufficient energy is required to participate in social activities and assume other role functions. Furthermore social functioning showed a positive correlation with role emotion (r = .752, p < 0.05) and mental health (r = .780, p < 0.05) suggesting that participating in social activities influences the roles assumed and impacts overall mental health perception furthermore role emotion had a positive correlation on mental health (r = .747, p < 0.05) suggesting that roles that are assumed have an impact on overall mental health (Table 12).

Spearman's Rho Correlation Coefficients Cardiac Arrest Group (Mental Health)

Table 12

Sp	Spearman's Rho Correlation Coefficients Cardiac Arrest Group (Mental Health)									
Variable	Age	Gender	Stay	BMI	Steps	SDS	VT	SF	RE	MH
Age	1.000	.289	658	164	.098	.356	222	390	456	525
Gender		1.000	.058	.232	507	.113	.057	.116	.234	.173
Stay			1.000	.420	.099	.267	325	032	.103	.266
ВМІ				1.000	086	191	.118	076	.121	.314
Steps					1.000	.144	229	049	148	.122
SDS						1.000	849*	790*	659	700
VT							1.000	.677	.857*	.568
SF								1.000	.752*	.780*
RE									1.000	.747*
МН										1.000

BMI=Body Mass Index, Avg=Average number of daily steps, SDS= Total Symptom Distress Score, VT= Vitality, SF= Social Functioning, RE= Role Emotion, MH= Mental Health *p=<0.05

In the non-cardiac arrest group, there was a negative correlation between length of stay in the hospital and average number of steps taken daily (r = -.755, p < 0.05) and physical component summary score (PCS), suggesting that as length of hospital stay increases the average number of daily steps taken decreases which negatively influences overall physical ability. There was a positive correlation between average number of steps taken daily and the physical component summary score (PCS) (r = .786, p < 0.05) suggesting as one's number of daily steps taken increases their overall physical ability increases. There was a negative correlation between physical component summary score

(PCS) and mental component summary score (MCS) (r = -.811, p < 0.05) suggesting that as overall physical ability decreases there is a negative impact on overall mental health (Table 13). Due to the fact that the PCS and MCS raw scores are made up of four subscales each, further exploration was needed to determine what factors were influential in this group

Table 13

Spearman's Rho Correlation Coefficients Non- Cardiac Arrest Group PCS and MCS Variable Gender Stay ВМІ Steps SDS PCS MCS Age 1.000 .529 -.633 -.655 -.145 -.636 .248 Age Gender 1.000 Stay 1.000 -.191 -.775* .019 -.756* .686 BMI 1.000 .252 -.234 .000 .445 Steps 1.000 .286 .786* -.703 SDS 1.000 .071 -.252 PCS 1.000 -.811* MCS 1.000

BMI=Body Mass Index, Steps=Average number of daily steps, SDS= Total Symptom Distress Score, PCS= \overline{P} hysical Component Summary, MCS= Mental Component Summary *p=< 0.05

In the non-cardiac arrest group for perceived functional capacity, there was a negative correlation between age and role perception (r = -.925, p < 0.05), suggesting that as age increases perceptions of their role and roles in daily life are not as involved. There was a negative correlation between length of stay and average numbers of steps (r = -

.775, p < 0.05), and length of stay with physical functioning (r = -.945, p < 0.05). These findings suggest that increased hospital stay significantly impacts physical activity levels. There was a positive correlation between body mass index and vitality (r = .836, p < 0.05). This finding suggest the increase in body mass index provided needed muscle and thus strength to perform activities of daily living; there was positive correlation with average number of steps with physical functioning (r = .857, p = < 0.05) (Table 14), suggesting that as the average number of steps taken daily increases, the ability to perform physical activities increases.

Spearman's Rho Correlation Coefficients Non-Cardiac Arrest Group (Perceived

Fi	unctional	Capacity)								
Variable	Age	Gender	Stay	ВМІ	Steps	SDS	PF	RP	GH	VT
Age	1.000	_	.529	633	655	145	527	925*	.083	376
Gender		1.000	-	-	-	-	-	-	-	-
Stay			1.000	191	775*	.019	945*	476	.706	.191
ВМІ				1.000	.252	234	.162	.519	.309	.836*
Steps					1.000	.286	.857*	.661	613	018
SDS						1.000	107	.055	342	505
PF							1.000	.569	631	090
RP								1.000	.056	.361
GH									1.000	.591
VT										1.000

BMI=Body Mass Index, Avg=Average number of daily steps, SDS= Total Symptom Distress Score, PF=Physical Functioning, RP= Role Perception, GH=General Health, VT= Vitality *p= ≤ 0.05

Table 14

In the non-cardiac arrest group for mental health, there was a negative correlation with length of stay and average number of steps (r = -.775, p = < 0.05), suggesting that the longer the stay in the hospital, the average number of steps taken each day decreases. There was a positive correlation between length of stay and role emotion (r = .826, p = < 0.05), suggesting that as the length of stay in the hospital increased, there was time to

^{**}p=< 0.01

reflect on individual roles, new roles and participation in daily activities. There was a positive correlation between body mass index, vitality and mental health (r = .836, p = < 0.05), (r = .773, p = < 0.05) respectively, suggesting that increases in body mass, which may represent increased strength and inductance which is important in maintaining mental and psychological well being. There was a positive correlation with vitality with social functioning (r = .802, p = < 0.05), suggesting that as energy level increases, the desire for social participation increases. Finally there were positive correlations between social functioning and role emotion (r = .769, p < 0.05) and social functioning with mental health (r = .925, p = < 0.05) (Table 15), suggesting that role emotion and mental health perhaps determines participation in social activities.

Spearman's Rho Correlation Coefficients Non-Cardiac Arrest Group (Mental Health)

Table 15

Sį	Spearman's Rho Correlation Coefficients Non-Cardiac Arrest Group (Mental Health)									
Variable	Age	Gender	Stay	BMI	Avg Steps	SDS	VT	SF	RE	MH
Age	1.000	-	.529	633	655	145	376	171	.271	193
Gender		1.000	-	-	-	-	-	-	-	-
Stay			1.000	191	775*	.019	.191	.495	.826*	.257
ВМІ				1.000	.252	234	.836*	.699	.278	.773*
Avg					1.000	.286	018	393	569	378
SDS						1.000	505	281	349	378
VT							1.000	.802*	.685	.736
SF								1.000	.769*	.925*
RE									1.000	.556
МН										1.000

BMI=Body Mass Index, Avg=Average number of daily steps, SDS= Total Symptom Distress Score, VT= Vitality, SF= Social Functioning, RE= Role Emotion, MH= Mental Health
*p=< 0.05

Multiple Regression

The first approach taken was the cardiac arrest group would be analyzed with average number of daily steps taken as the dependent variable with symptom distress, physical functioning, role perception, general health and vitality as dependent variables. A second regression was completed with mental health as a dependent variable and average number of daily steps, symptom distress, physical functioning, role perception,

general health and vitality as independent variables. Subsequent analysis consisted of following the same procedure with the non-cardiac arrest group.

Multiple regression analyses were performed to determine which variables accounted for more of the variance with average number of daily steps and mental health. Variables were selected from the correlation matrix that demonstrated significance. The overall findings showed that for the cardiac arrest group with average number of daily steps as dependent variable, symptom distress, physical functioning, role perception and general health explained 95% of perceived functional capacity with all variables being significant ($p = \langle 0.05 \rangle$) (Table 16). There was no significance found in the cardiac arrest group in regards to mental health and selected variables.

Table 16

Regression Analysis of Cardiac Arrest group Perceived Functional Capacity, Steps as
Dependent Variable

Model

	Unstandardized Coefficie	nts	Standardized Coefficients	F
	Beta	SE	Beta	
Intercept (Steps)	-51781.8	5372.098		-9.639
Symptom Distress	931.499	94.561	2.725*	9.851
Physical Functioning (PF)	356.843	48.007	1.305*	7.433
Role Perception (RP)	-256.343	41.793	858*	-6.134
General Health (GH)	618.301	82.302	2.334*	7.513
Adjusted R ²	.958			

SE= standard error.

^{*}*p* < 0.05

The non cardiac arrest group with average number of daily steps as the dependent variable, symptom distress and physical functioning explained 63% of perceived functional capacity with physical functioning being significant (p = < 0.05) (Table 17). There was no significance found in the cardiac arrest group in regards to mental health and selected variables.

Table 17

Regression Analysis of Non-Cardiac Arrest group Perceived Functional Capacity, Steps as Dependent Variable

	Model			
	Unstandardized Coefficients		Standardized Coefficients	F
	Beta	SE	Beta	
Intercept (Steps)	-12067.3	8899.196		-1.356
Symptom Distress	126.297	340.280	.092	.371
, ,				
Physical Functioning (PF)	425.281	120.368	.872*	3.533
2				
Adjusted R ²	.636			

SE= $standard\ error$.

^{*}*p* < 0.05

The qualitative questions answered provide clarity and validation to findings from the correlations and regressions models conducted. In the cardiac arrest group, role perception and perception of good mental health were important to physical and social functioning. One participant stated, "I don't go out as much with my family, like going out to eat." "When I feel like I have the energy is usually when I'll call my daughter and say I would like to go somewhere and she drives me." Another participant said, "I look at my children longer. I don't know what they would have done if I were gone." "I enjoy each day I have with my family".

Average number of steps taken daily was associated with decreased physical activity, perception of health status and energy level. One participant stated, "I don't have the energy that I had before." "I'm very careful at things I do around the house." "I still have a lot of nausea with the medications I'm taking." "I wish the doctor would listen to me more. I tell him about the nausea from the medications and all he says I need to take them, it will go away."

A significant number in the cardiac arrest group voiced the concern of the provider listening to their symptoms and explaining plan of care in terms they could understand. Not having this process placed a sense of vulnerability and unknown on the participants. Examples include statements like, "Probably listening to me as I have said to the doctor several times about my medications, they just upset my stomach." I wish the doctor would listen to me more. I tell him about the nausea from the medications and all he says I need to take them, it will go away." Another states, "I'm on a lot of medications and sometimes it can be confusing." In terms of clarifying plan of care one participant said, "Specifically cardiologist spoke another language, needed someone to turn to for

explanation of what he said." "Language barrier big problem." Another said, "Make sure you talk and explain what is going on." "I think that was scary for me as sometimes, I did not understand some of the medical terms."

There was an overall gratefulness for the care that was provided, examples include, "The nurses and doctors have been great, I can't say enough about them." "I owe them a lot." "They saved my life and I'm grateful." Another stated, "The most helpful was just having someone explain to me all the medical terms that I didn't understand." "The nurses that took care of me in the ICU were great." "They were great to me and my family." "I still see them since I work here, so I see them when I make rounds." See Appendix H for full qualitative questions and answers provided by the cardiac arrest group.

In the non-cardiac arrest group physical functioning was important in social activity and role participation. This was supported by the qualitative questions answered, examples include: "More specific was the stroke I had, I can't go places like I use to." "Me and my wife traveled six months out of the year, but not as much now." "It's my physical abilities, can't do as much." "I have slowed down, don't do as many things as use to do." "I think it's mental, misgivings things like that, it's really been the last 5 years." "I can do certain things." "Two days a week I work at the park and service center with the children." "What I do has changed to a certain point, I have to sit down more often, but that's okay, I am answering phones, it helps and I like doing it." "Use to walk 5 miles, now only walk about a mile or mile and a half." "On the go all the time." "Still weak, I know my limitations, that's just part of living."

Of significance for the non-cardiac arrest group was that of participation in cardiac rehabilitation, as it was significant in their social activity and role perception, examples include: "Seminar I attended had a lot of information, very helpful, all cardiac patients were there." "Nurses particularly rehab very good." "I have no memory of the first 3 weeks in the hospital, but the first thing I remember was going to rehabilitation." " No improvements, everybody has been great, Intensive care was great to my wife." " Cardiac rehab instrumental in giving positive outlook, one on one and the peer participation." See Appendix I for full qualitative question and answers provided by the non-cardiac arrest group. This was an important finding as the cardiac arrest subjects had never participated or were referred to a cardiac rehabilitation program, signifying the importance of social interaction and participation in structured activity such as cardiac rehabilitation. The findings of Barnason et al. (2000), support this as their study demonstrated rebound of both physical and social aspects of functioning in the early posthospitalization for some distinct areas of functioning. Barnason et al. (2000) suggested interventions to improve functional status might include symptom management, individualized cardiac rehabilitation, psychosocial support and the use of technologies for cardiac arrest patients in attaining optimum functional status and reducing coronary artery disease risk factors.

CHAPTER 5

Findings

Summary

The purpose of this descriptive study was to describe functional status in individuals who survived a cardiac arrest with no cognitive impairments and were discharged home. Leidy's framework provided a theoretical foundation for this investigation because cardiac arrest survival is low, two strategies were implemented to enhance the study findings and to explain functional status in this unique population. One strategy included a comparison group of non-cardiac arrest, myocardial infarction subjects, who were actively engaged in a cardiac rehabilitation program. The second strategy was by way of three qualitative questions to make the understanding of the quantitative data more robust and validate the quantitative findings.

Overall significant findings suggested that in the cardiac arrest group, symptom distress had a negative influence in the ability to participate in social activities and roles at work or within family settings. Symptom distress also had an inverse relationship in the total number of daily steps taken as symptom distress increased, daily average steps decreased suggesting that control of symptoms such as nausea and fatigue are important factors in functional status and mental health in the population.

In the non-cardiac arrest group, physical functioning, the ability to perform physical activities had a positive influence on their control of symptom distress, participation in social activities and role perception, suggesting that an increased number of daily steps taken daily increases participation in social activities and increases role perception. The non-cardiac arrest group had a higher number of daily steps than the

cardiac arrest group (5819, SD \pm 4602) vs. (4392, SD \pm 3469) respectively and this could be accounted for by the fact the non-cardiac arrest subjects participated in cardiac rehabilitation twice a week on a regular basis for eight weeks.

Earlier studies attempted to measure functional status, but did not clearly captured the concept and used quality of life interchangeably with functional status. There are limited studies that have used the post cardiac arrest survivors as a population of study. Additionally, previous studies used a single parameter to measure functional status, thus increasing the difficulty comparing results of this study to the body of literature. However the findings from this study are similar in some respects with a study conducted on the long-term physical functioning and psychosocial adjustment in survivors of sudden cardiac death (Sauve, 1995). It should be noted that the Sauve study was conducted in 1984 and published 10 years later in 1995 and consisted of cardiac arrest survivors from a minimum of six months to as long a three years out from the cardiac arrest event. In the Sauve study, The Health Status Questionnaire, which consisted of two Rand Corporation instruments: the Physical Functioning Index and the Mental Index, which now is the SF-36 General Health Survey was one of the instrument used to assess physical functioning and mental health. In the Sauve study, the conclusion was "despite decreases in physical functioning, only a minority of sudden cardiac death survivors is severely psychologically distressed. Illness severity was a strong predicator of physical functioning, but its contribution to psychological distress is indirect, acting largely through the aegis of poor physical functioning and loss of pre-arrest work status" (Sauve, 1995, p 134).

This study bridges the gap in the body of literature regarding post cardiac arrest survivors and provides a beginning in evaluating their progress once discharged to home. Using Leidy's framework, this study demonstrated that functional status encompasses many aspects of one's life, such as their physical ability, social interaction, roles used to participate in daily life, mental health and the overall energy level they experience. Once these variables are evaluated and tested, then we can begin to clearly describe one's functional status and begin to identify both objectively and from the survivors' perspective those factors that either positively or negatively affect recovery in this patient population.

According to Wang (2004), a human 'possesses ability' to perform activities necessary for daily life, there are 'normal expectations' regarding human activities and the necessities of life can be realized through individual activities. The consequences of functional status are that it is maintained and or impaired. If functional status is maintained, one could actively participate in his/her life. However, if functional status cannot be maintained, certain difficulties in activities of daily life will be experienced and may eventually lead to a limited level of functioning and a degree of disability. This was demonstrated by the fact that the cardiac arrest group had less average number of daily steps, although not statistically significant, the cardiac arrest group demonstrated an increase in symptom distress impacting overall physical performance, possible role participation and roles assumed in daily activity.

Perceived Functional Capacity Cardiac Arrest Group

Perceived functional capacity, is one's maximum potential to perform those activities individuals do in the normal course of their lives to meet basic needs, fulfill

usual roles, and maintain their health and well-being. The term refers to potential in any domain including physical, cognitive, psychological, social, spiritual and sociodemographic (Leidy 1994). Perceived functional capacity was measured in this study with the subscales of the SF-36: Physical Functioning (PF), Role-Physical (RP), General Health (GH) and Vitality (VT), which together make the physical summary component (PCS) of the SF-36. Since the SF-36 has limited use with a post cardiac arrest population, critical evaluation of the PCS and subscales were completed to best describe perceived functional capacity in this population.

In the cardiac arrest group, correlations were completed with the age, gender, length of stay, body mass index, average number of daily steps, symptom distress scores and overall PCS score. The correlations demonstrated no significance within the cardiac arrest group when analysis was conducted using the overall PCS score, suggesting that the PCS score alone was too broad and further analysis was needed to determine what specific variable was influential on functional status. Further exploration of the data using the subscales that compose the SF-36 PCS summary measure, (PF, RP, GH and VT) suggest as symptom distress increases, their physical ability to perform physical activities decreases, their perception of general health decreases and overall energy level fall. However, as one's role participation increases, their physical activities and overall general health and well-being increase, thus having a positive influence on the average number of steps taken daily. Most of the variance in the average number of daily steps taken was explained by symptom distress, general health, physical functioning and role perception being significant. This suggests these factors can either have a positive or negative affect on physical performance, social participation, roles they choose to assume

and overall general health that together explains perceived functional capacity.

Participating in a cardiac rehabilitation program could improve symptom distress, thus improving physical performance, role participation and participation in social activities.

Mental Health Cardiac Arrest Group

In the cardiac arrest group, correlations were completed with age, gender, length of stay, body mass index, average number of daily steps, symptom distress scores and MCS score. The correlations demonstrated no significant difference within the cardiac arrest group when analysis was conducted using the overall MCS score. Further exploration of the data using the subscales that compose the SF-36 MCS summary measure, (SF, RE, MH and VT) suggest symptom distress has a negative impact on perception of one's mental health and overall available energy, which could influence participation in social activities.

As an individual's energy level increases, their participation in social activities and role function increase suggesting a positive influence on mental health with the most influential variable being energy level, (i.e. vitality). These findings support the theory that there is more than one factor that influences one's functional status and mental health and these aspects need to be evaluated to assess one's functional status. This finding was further supported by the qualitative analysis of statements from the cardiac arrest group, such as "I don't go out as much with my family, like going out to eat." "When I feel like I have the energy is usually when I'll call my daughter and say I would like to go somewhere and she drives me." "I enjoy each day I have with my family."

Perceived Functional Capacity Non-Cardiac Arrest

In the non- cardiac arrest group, correlations were completed for age, gender, length of stay, body mass index, average number of daily steps, symptom distress scores and PCS score. The correlations demonstrated a negative correlation with length of stay in the hospital, average number of steps and overall PCS score suggesting in this group the longer one stays in the hospital the less number of steps taken daily or the longer it takes to complete rehabilitation. However, there was positive correlation with average number of steps and PCS scores demonstrating as the number of steps increase the over all physical score increases. Further exploration of the data using the subscales that compose the SF-36 PCS summary measure, (PF, RP, GH and VT) suggest as age increases, perception of their roles and roles in daily life are less involved and as hospital stay increases, physical ability is decreased. On the other hand, as body mass index increased, their perception of energy level increased, suggesting that an increase in muscle mass and thus energy, influences the ability to perform daily activities. Also noted was as the number of daily steps increased, the perception to perform more daily activities increased. The most influential variable was physical functioning on functional status, suggesting the ability to perform physical activity was an important variable in their perceived functional capacity. This was supported by the fact they were actively engaged in cardiac rehabilitation two times a week having social interaction with peers. Mental Health Non-Cardiac Arrest Group

In the non-cardiac arrest group, correlations were completed with the age, gender, length of stay, body mass index, average number of daily steps, symptom distress scores and MCS score. The correlations demonstrated that age, body mass index and overall

MCS score were significant related to mental health. Further investigation of the data using the subscales that compose the SF-36 MCS summary measure, (SF, RE, MH and VT) suggest that the longer the stay in the hospital, the average number of steps taken decreased, but role perception increased therefore suggesting the individuals had time to reflect on their new roles and participation in daily activities. As body mass index increased, vitality, mental health and social functioning increased, signifying that the perception of increased energy reserve improved mental health and participation in social activities. As role and mental health increased, yet again participation in social activities increased.

Physical Functional Performance

This variable was measured by the energy expenditure for seven days recorded as energy expenditure, average number of daily steps taken, with the New-Life Style 2000 Activity Monitor. Electronic pedometers are widely accepted among physical activity researchers over the past decade. Researchers have commonly used them in physical interventions, especially those that use walking as the primary mode of activity (Bassett & Strath, 2002). In addition, pedometers or activity monitors, such as the New-Life Style 2000, are often used as an adjunct to physical activity questionnaires, since researchers recognized the advantage of having a simple, accurate, and objective measure of energy expenditure (Bassett & Strath 2002; Tudor-Locke, Williams, Reis, & Pluto, 2002).

Using the NL-2000 as the actual energy expenditure measurement with the SF-36 as a measurement of the sample's perceived functional capacity demonstrated that one's actual energy expenditure is related to one's physical ability and role perception. The non-cardiac arrest group (n=7) averaged 5,819 steps/day, as compared to the cardiac

arrest group (n=8) average steps/day was 4,392 however, there was no significant difference found between the two groups. Furthermore, the non-cardiac arrest, myocardial infarction group was actively engaged in cardiac rehabilitation post MI twice a week for eight weeks. As the findings suggests, perceived functional capacity and mental health for the non-cardiac arrest group are related to age, physical abilities, role perception and participation in social activities, which all were related to an increased energy level whereas by participating in cardiac rehabilitation twice a week supports. *Symptom Distress*

Symptom Distress is defined as the somatic, concentration and affective discomfort presently being experienced by the patient and self reported with the Symptom Distress Scale (SDS). McCorkle (1987) found a correlation of .90 between Symptom Distress scores and scores on the Ware et al. (1994) Health Perception questionnaire (SF-36) demonstrating convergent validity of the tool. The SDS discriminates between survivors of myocardial infarction and patients with cancer (McCorkle & Quint-Benoliel, 1983), as well as between patients with home care and with healthy controls.

Scores on the Symptom Distress range from 13 to 65, the higher the score the more symptom distress. Cowan, Graham & Cochran (1992) conducted a study with post myocardial infarction patients (n=27) using the symptom distress scale. The symptom distress score was not reported. McCorkle & Quint-Benoliel (1983) conducted a study on myocardial infarction patients two months post diagnosis of a myocardial infarction (n=65) and reported the SDS mean score of 19.2 ± 4.9 . To best explain the population for this study the 6 months post event the mean score of 22.2, SD ± 7.1 was used as

McCorkle, R., Yost, L.S., Jepson, C., Malone, D., Baird, S. & Lusk, E. (1993) reported this in patients 6 months after discharge from the hospital. For this study (n = 15) the mean score was 24, SD = 7.78, p = .386 signifying no significant difference in the study sample to those discharged six months from the hospital.

Symptom Distress Cardiac Arrest Group

Symptom distress was a factor in perceived functional capacity and mental health in the cardiac arrest group as symptom distress increased, physical ability, overall general health, energy level and participation in social activities decreased. This finding suggests that improving symptoms such as nausea or fatigue improves physical performance and mental health in functional status. This finding was supported by the qualitative findings, as this was a common reported theme with the cardiac arrest group. Examples include; "I don't have the energy I had before." "I still have a lot of nausea with the medications I'm taking." "I wish the doctor would listen to me more. I tell him about the nausea from the medications and all he says I need to take them, it will go away." Another stated "Probably listening to me as I have said to the doctor several times about my medications, they just upset my stomach."

Symptom Distress Non-Cardiac Arrest Group

Symptom distress was not related to the perceived functional capacity and mental health in the non-cardiac arrest group. More important were factors such as age, length of stay in the hospital and average number of steps taken daily, as these were related to physical ability, their role perception and participation in social activities. This finding could be explained by the fact that the non-cardiac arrest group are actively engaged in cardiac rehabilitation which has an emphasis on improving physical health which impacts

symptoms experienced. This finding was supported by the qualitative responses such as "Seminar I attended I attend had a lot of information, very helpful, all cardiac patients were there." "Cardiac rehab instrumental in giving positive outlook, one on one and the peer participation."

Predicting Functional Status In Post Cardiac Arrest Survivors

If predictors of perceived functional capacity and mental health in post cardiac arrest survivors can be identified early in the post discharge period, interventions can be developed to improve perceived functional capacity and mental health. When evaluating all the variables to perceived functional capacity and mental health in both the cardiac arrest group and non-cardiac arrest group, vitality or energy level explained 58% of the variance in the cardiac arrest group and 77% in the non-cardiac arrest group. This is an important finding to critical care providers as interventions can be provided at discharge that improve overall energy level that impacts participation in social activities, increased average number of steps taken and participation in social activities. Included in the predictors would be factors such as control of symptoms in the cardiac arrest group as the findings reported nausea, fatigue and vitality were a major complaint in this group, indicating that more education and evaluation of medication regimes are needed. Treating these symptoms has the potential to dramatically improving the post cardiac arrest survivor's quality of life, thus impacting perceived functional capacity and mental health.

Overall, this is a small sample of cardiac arrest survivors and non-cardiac arrest, myocardial infarction subjects. Since this study was conducted in the San Diego County by means of public advertisement, it is only reflective of those individuals who responded

to the advertisement. This study is a beginning to understanding the phenomenon of surviving a cardiac arrest and implementing outcomes directed at improving physical performance and limiting symptom distress, which would have a positive influence on functional status and mental health. Conducting this study differently would include expanding the sample size; include a larger area of recruitment and seeking approval through several large medical facilities as an effort to capture this population thoroughly and including a larger number of female subjects.

This study provides data on what factors in functional status and mental health in this population may be more fruitful to explore. It provides a beginning of where researchers, nurses and health care providers should focus care once the cardiac arrest survivor has been discharged to home. Knowing what is needed for this population may improve the recovery time from the event and improve physical performance, participation in social activities and assumption of roles at work and with family. Areas that need to be considered are the long-term effects of cardiac arrest, as this study does not provide reflection into this area. Future studies should focus on longitudinal changes and measuring one's functional status overtime, such at 3 months, 6months, 9 months and one year, as this study was focused only on a seven-day period and it did not determine if once changes occur do they last over extended periods of time.

Study Reliability and Validity

Reliability of Measures in Cardiac Arrest Survivors

Because the instrument had rarely been used in the cardiac arrest survivor population, reliability in this population was uncertain. Reliabilities for the SF-36 summary scales, PCS and MCS were impressive (.80 and .88) respectively, when used to

rate perceived functional capacity and mental health in survivors post cardiac arrest, however the sub-scales proved to explain the phenomenon more specifically. This instrument was easy for the subject to read and complete and there was software included to assist in the interpretation of results. Scoring the SF-36 was done by using a format suggested by the manufacturer to enter data on a Microsoft excel spread sheet, then transferring data into the SF-36 scoring software. These scores were then transferred into SPSS to calculate sum scores. This tool should be useful to researchers in future studies of cardiac arrest survivors. One barrier to using the instrument for some researchers may be the cost; total cost for the reference kit and Outcomes scoring software was \$307.49.

The standard Mini Mental State Exam used for this study was a quick, useful, and economical method of obtaining cognitive ability data. The tool took less than 3 minutes for the participant to complete; was easy for the subject to read and complete and there was no cost to the researcher to use the tool. It provided a total score based on age and educational level to assess if the participant could read and understand the questionnaires asked to complete. This tool can be used in participants in the hospital as well as after being discharged and may be used to assess any changes in cognitive ability over time.

The SDS was a reliable tool for use in the cardiac arrest survivor to measure symptom distress. Total scale reliability was .90, which is higher than previously reported in subjects discharged from the hospital within 6 months (McCorkle, 1984). This instrument was easy for the subject to read and complete and there was no cost to the researcher to use the tool.

The New Lifestyle 2000 activity monitor (NL-2000) proved to be a useful way of measuring actual energy expenditure by the subjects. The NL-2000 Activity monitor has

incorporated into the device self-calculation for energy expenditure based upon age, sex. height, weight which calculates the average number of daily steps taken. It measures vertical acceleration (i.e., up and down motion) and total caloric expenditure (i.e., the calories one's body burns to keep functioning properly plus the calories one expends through exercise or activity). When positioned correctly on the hip, the New-Life Style 2000 Activity Monitor records a step each time the hip moves up and down. The activity monitor also measures activities one does throughout the day in addition to walking (e.g., bending to tie one's shoes, going up and down stairs). One barrier to using this instrument for some researchers may be the cost; \$54.95 per instrument. For this study the participants were offered the instrument as a gift and a means of maintaining activity level and progress.

Internal Validity

Public advertisement was the process to obtain subjects for this study. This approach was used because of HIPPA regulations in surrounding facilities in the San Diego County. There were many barriers to access databases in finding subjects discharged from the hospital post cardiac arrest; therefore the approach taken was to obtain as many subjects as possible via advertisements placed in the local newspaper on a Thursday and Saturday in the central, east and south zones, running the advertisements twice, which totaled readership of 260,629, advertisement in the Weekly Reader with a totaled readership of 797,500, public announcement on a local am radio station, KLSD-AM broadcasting four times a day for 4 days, placement of advertisement on a near death experience website and advertisement in local community meeting establishments such as VFW's. The advertising took place from February 17th, 2005 to May 5th, 2005. A barrier

to using this approach for some researchers may be the cost; advertising in the newspaper-\$1,800, Weekly Reader- \$1,034 for seven days, and radio announcements-\$900. However, there was no cost associated with placement of ad on website or posting in VFW.

Cardiac arrest survival has previously been reported low (5-13%), but is increasing due to automatic external defibrillators use, public training and awareness of cardiac arrest. The survival rate is nearing 45%, so the expectations were potential subjects that read or heard the advertisement would respond if interested or give the information to someone who had experienced a cardiac arrest. There were a total of twenty responses, two from the radio advertisement, one from the VFW posting, ten from the local newspaper and seven from the Weekly Reader. This number was above previous studies evaluating cardiac arrest patients, as many studies reported on average one patient per month surviving and their means of obtaining patients were through hospital facilities. A total of five participants were excluded for various reasons, confusion of a panic attack with cardiac arrest, did not meet minimum age or refused because they were going on vacation.

All subjects that voluntarily participated were glad to participate and share their experience. There was concern that the subjects would not want to discuss or reflect upon their event or they would not have the energy to participate and wear the activity monitor for seven days. However the opposite was seen, as they wanted to share their experience, were eager to wear the NL-2000 activity monitor and then see what their daily steps would be at the end. The expectation was that after seeing their actual steps there would be a positive influence on their activity level. This occurred in several participants

including one individual who was a Left Ventricular Assist Device (LVAD) patient and a cardiac arrest survivor, who before the study was depressed and contemplating removing the (LVAD) because he could no longer do the activity he once could do. Several weeks after completing the study, his outlook has changed and he has increased the walking on the treadmill by two levels, this being related to now he can see and measure his daily progress.

Usefulness of Model

The framework used for this study, Leidy's Functional Status combined with the self-reporting SF-36 General Health Survey, Symptom Distress Scale, Qualitative questions and the New Lifestyle 2000 Activity monitor was an appropriate model to guide the design and implementation of this study in post cardiac arrest survivors.

Leidy's framework nor the instruments with the exception of the SF-36 have been used in this population. Perceived functional capacity and mental health were influenced by numerous variables, all of which could be labeled as either a physiological, psychological or situational factors. Use of this framework allows researcher to evaluate the contributions or predictors of perceived functional capacity and mental health, which will aid in designing interventions to improve outcomes after discharge from the hospital.

Research using this framework and design in a larger sample size in a longitudinal study will add further knowledge and understanding of perceived functional capacity and mental health in post cardiac arrest survivor. The model provides a critical evaluation of those specific factors that are associated with functional status and which factors are in need of support to improve functional status in this population. The authors of previous studies recognized the cardiac arrest survivor, but focused on only one aspect in

determining functional status. Instead of studying functional status as an isolated variable interchangeable with quality of life, future studies might focus on all the variables associated with perceived functional capacity and mental health that act as a catalyst to worsen or improve functional status.

The model could be used to guide research concerning how the predictor variables not only influence perceived functional capacity and mental health, but also compound the severity of functional status. For example, vitality and physical ability, average number of steps taken, role perception and social interaction correlated with both groups. Further exploration of these relationships and interventions to improve perceived functional capacity and mental health could significantly influence functional status.

The model does not explain that once a level of functional status has been obtained what measures are needed to maintain a productive level. Though the model described social functioning and role perception were important factors to the cardiac arrest survivor it did not explain the impact of the arrest event and changes in the survivors physical function on the survivors' spouse or other family members needs.

Conclusions

The purpose of this study was to describe perceived functional capacity, physical performance, mental health, symptom distress, and demographic variables in the post cardiac arrest survivor discharged to home and describe the relationship among these variables. The cardiac arrest group and non-cardiac arrest group both showed that energy level, (vitality), physical abilities to perform activities (physical functioning), roles fulfilled in life (role perception) and involvement in social settings (social functioning) were important factors in perceived functional capacity and mental health. Also

recognized was the fact that these variables were influenced by the level of symptom distress experienced and physical ability as determined by the average number of steps taken daily.

Based on findings from this study, early identification and intervention of perceived functional capacity and mental health can improve overall functional status. After they are discharged from the hospital, the post cardiac arrest patient has contact with a variety of healthcare providers. Specifically, nurses could be the key to intervening and promoting positive outcomes. The interaction between the cardiac arrest survivor and the nurse serves as an opportunity for the nurse to assess the individual's symptoms experienced, energy level and participation in physical activity as well as role and social interaction, listen empathetically, and provide nursing interventions specific to the problems the cardiac arrest survivor is facing. Nurses in the clinics where the arrest survivor is seen for follow-up care can assist in identifying patients with problems, educating them about available resources that might assist in alleviating the problems, and by communicating their nursing assessment to the physician or critical care nurse practitioner for follow-up.

Recommendations for Further Research

The concept of functional status is complicated because it has been used interchangeably with quality of life or single parameters have been used to measure functional status. Cardiac arrest survivors are a unique population with few studies conducted on their behalf. This population is growing due to public awareness of what is a cardiac arrest and how to respond, training of lay personnel in the use of the automatic external defibrillator and training in advanced cardiac life support by the American Heart

Association standards. Study findings suggest that assessment of and treatment for the psychological and physiological findings of cardiac arrest survivors might improve overall functional status in this population, thus improving their physical abilities and participation in role and social interactions. Leidy's framework of functional status can be used as a guideline to extend the study of functional status in cardiac arrest survivors.

The findings suggest that perceived functional capacity and mental health in this small sample size requires further exploration. Future research could focus on physical abilities, energy levels, role and social participation on a larger population over a longer period of time to assess changes to determine if changes in perceived functional capacity and mental health improve overall functional status and determine if these changes are maintained.

Research could also concentrate on assessing their level of functioning before the arrest, identifying those who may be at high risk or have a history of life-threatening arrhythmias and determining their level of functional status immediately after the arrest as this would provide fruitful information on what impact surviving a cardiac arrest has on one's functional status; however this would be challenging, as no one knows when someone will suffer a cardiac arrest making this object difficult to achieve.

In this study, similarities were noted between research previously conducted was to determine functional status; however this research were based on single variable to overall functional status. This study demonstrated there are multiple variables that impact one's functional status and it is imperative that healthcare provider seek and understand the most important factors that influence one's perceived functional status and mental health as this has significant importance in the cardiac arrest survivor's recovery.

Future research focused on the distinct context of the cardiac arrest survivor's recovery may add substantially to our knowledge of this population.

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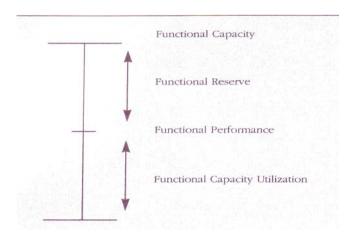
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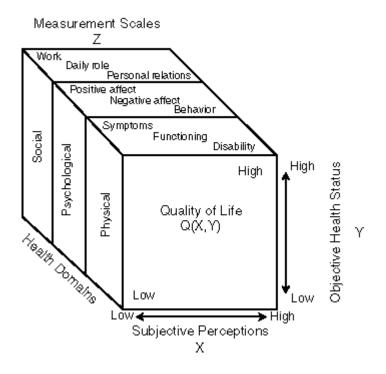
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Appendix A: Functional Status Framework



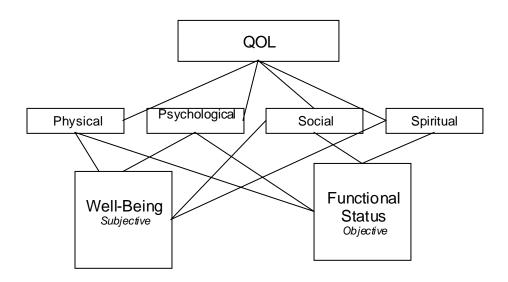
(From "Functional Status and the Forward Progress of Merry-Go-Rounds: Toward a Coherent Analytical Framework," by N.K.Leidy, 1994, Nursing Research, Vol.43, No.4, p.198.)

Appendix B: Assessment of Quality of Life Outcomes



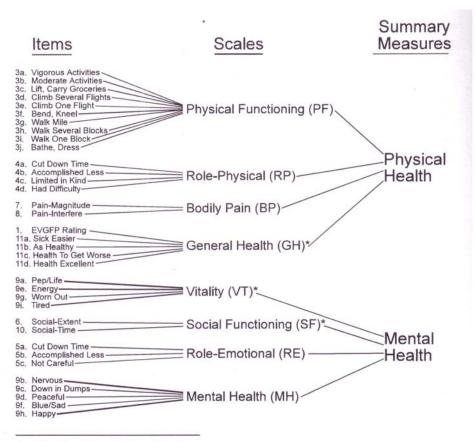
(From "Assessment of Quality-Of-Life Outcomes," by M.A. Testa and D.C. Simonson, 1996, New England Journal of Medicine, Vol.334, No.13, p.836.)

Appendix C: Quality of Life Diagram



(From "Clarification and Integration of Similar Quality of Life Concepts," by B.K. Haas, 1999, New England Journal of Medicine, Vol.31, No.3, p.10.)

Appendix D: SF-36 Scale



^{*} Significant correlation with other summary measure.

(From "SF-36 Physical and Mental Health Summary Scales: A User's Manual" by J. E. Ware, 1994, 5th Edition, Chapter 3, p.3:2)

Appendix E: SF-36 Health Survey

SF36 Health Survey

INST	FRUCTIONS: This set of questions asks for your views about y nelp keep track of how you feel and how well you are able to do	our health	. This informal activities	nation Answer
	y question by marking the answer as indicated. If you are unsi			
	stion please give the best answer you can.			T. 1 (177)
1.	In general, would you say your health is: (Please tick one be Excellent)x.)		
	Very Good □			
	Good 🗆			
	Fair □ Poor □			
2.	Compared to one year ago, how would you rate your health in ge	neral now?	(Please tick	one box.)
2.	Much better than one year ago		(, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,
1	Somewhat better now than one year ago			
	About the same as one year ago Somewhat worse now than one year ago			
	Much worse now than one year ago			
3.	The following questions are about activities you might do during a now limit you in these activities? If so, how much? (Please cir		/. Does your	
		Yes,	Yes,	Not
	Activities	Limited	Limited A	Limited
	Activities	A Lot	Little	At All
3(a)	Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
3(b)	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
3(c)	Lifting or carrying groceries	1	2	3
3(d)		1	2	3
3(e)	Climbing one flight of stairs	1	2	3
3(f)	Bending, kneeling, or stooping	1	2	3
3(g)	Waling more than a mile	1	2	3
3(h)	Walking several blocks	1	2	3
3(i)	Walking one block	1	2	3
3(j)	Bathing or dressing yourself	1	2	3
4.	During the <u>past 4 weeks</u> , have you had any of the following proble regular daily activities <u>as a result of your physical health?</u> (Please circle one number on each line.)	ems with yo		
4(a)			Yes	No
37. 70	Cut down on the amount of time you spent on work or other active	ities	1	2
4(b)	•••••••••••••••••••••••••••••••••••••••			2
4(c)	Were limited in the kind of work or other activities			2
4(d)	Had difficulty performing the work or other activities (for example, it took 1 2 extra effort)			
5.	During the <u>past 4 weeks</u> , have you had any of the following proble regular daily activities <u>as a result of any emotional problems</u> (e.g. f (Please circle one number on each line.)	ms with you eeling dep	ur work or oth ressed or anx Yes	ier ious)? No
5(a)	Cut down on the amount of time you spent on work or other activi	ties	1	2
5(b)	Accomplished less than you would like		1 1	2
5(c)	Didn't do work or other activities as carefully as usual		1	2
-	and the same and t			

Appendix E: SF-36 Health Survey

6.	During the <u>past 4 weeks</u> , to what extent with your normal social activities with far Not at all						
	Slightly						
	Moderately						
	Quite a bit						
	Extremely						
7.	How much <u>physical</u> pain have you had o	during the pas	st 4 week	s? (Please	tick one	box.)	
	Very mild						
	Mild						
	Moderate						
	Severe						
•					- 10 min o	20 00 10	
8.	During the <u>past 4 weeks</u> , how much did outside the home and housework)? (Ple	pain interfere	with you	ir normal wo	ork (inclu	ding bot	n work
	Not at all	ase lick one i	box.)				
	A little bit						
	Moderately						
	Quite a bit						
	Extremely						
9.	These questions are about how you feel and how things have been with you <u>during the past 4</u> weeks. Please give the one answer that is closest to the way you have been feeling for each item.						
	ALANCE CONTROL AND ARTHUR ADVISOR OF THE ACTION OF	All of the	Most of the	A Good	Some	A Little	
	(Please circle one number on each line.)	Time	Time	Bit of the Time	of the Time	of the Time	of the Time
9(a)	Did you feel full of life?	1	2	3	4	5	6
9(b)	Have you been a very nervous person?	1	2	3	4	5	6
9(c)	Have you felt so down in the dumps that	1	2	3	4	5	6
	nothing could cheer you up?						
9(d)	Have you felt calm and peaceful?		2	3	4	5	6
9(e)	Did you have a lot of energy?		2	3	4	5	6
9(f)	Have you felt downhearted and blue?	1	2	3	4	5	6
9(g)	Did you feel worn out?	1	2	3	4	5	6
9(h)	Have you been a happy person?	1	2	3	4	5	6
9(i)	Did you feel tired?	1 1	2	3	4	5	6
10.	During the <u>past 4 weeks</u> , how much of th interfered with your social activities (like vall of the time	e time has yo visiting with fr	our <u>physi</u> iends, re	cal health o latives etc.)	r emotio (Please	nal probl tick one	ems box.)
	Most of the time						
	Some of the time						
	None of the time						
11.	How TRUE or FALSE is each of the follow	wing stateme	nts for yo	ou?			
	(Please circle one number on each line.)						
	(Flease circle one number on each line.)	Definitely True	Mosti True			stly D	Definitely False
11(a)	I seem to get sick a little easier than other people	1	2	3	4		5
11(b)	I am as healthy as anybody I know	1	2	3			5
11(c)	I expect my health to get worse	1	2	3	4		5

105

Appendix: F

SYMPTOM DISTRESS SCALE

Instructions

Below are 5 different numbered statements. Think about what each statement says, then place a circle around the one statement that most closely indicates how you have been feeling lately.

The statements are ranked from 1 to 5, where number one indicates no problems and number five indicates the maximum amount of problems. Numbers two through four indicate you feel somewhere in between these two extremes. Please circle one number on each card.

	•	es of Distress ausea (1)		
1	2	3	4	5
I seldom if ever have nausea	I have nausea once in a while	I have nausea fairly often	I have nausea half the time at least	I have nausea continually
	N	ausea (2)		
1	2	3	4	5
When I do have nausea, it is very mild	When I do have nausea, it is mildly distressing	When I have nausea, I feel pretty sick	When I have nausea, I usually feel very sick	When I have nausea, I am as sick as I could possibly be
	A	Appetite		
1	2	3	4	5
I have my normal appetite and enjoy good food	My appetite is usually, but not always, pretty good	I don't really enjoy my food	I have to force myself to eat my food	I cannot stand the thought of food

Appendix F: Symptom Distress Scale

Degrees of Distress

Insomnia

1	2	3	4	5
I sleep as well as I always have	I occasionally have trouble getting to sleep and staying	I frequently have trouble getting to sleep	I have difficulty getting to sleep and staying asleep	It is almost impossible for me to get a decent
	asleep		almost every night	night's sleep
]	Pain (1)		
1	2	3	4	5
I almost never have pain	I have pain once in a while	I have pain several times a week	I am usually in some degree of pain	I am in some degree of pain almost constantly
	1	Pain (2)		
1	2	3	4	5
When I do have	When I do have	When I do have	The pain I have is	The pain I have is
pain, it is very	pain, it is mildly	pain, it is usually	very intense	almost unbearable
mild	distressing	fairly intense		
		Fatigue		
1	2	3	4	5
I seldom feel tired	There are periods	There are periods	I am usually very	Most of the time,
or fatigued	when I am rather	when I am quite	tired and fatigued	I feel exhausted
	tired or fatigued	tired and fatigued		
		Bowel		
1	2	3	4	5
I have my normal	My bowel pattern	My present bowel	I am usually in	I am in almost
bowel pattern	occasionally causes me some	pattern occasionally causes me	considerable discomfort because	constant discomfort
	discomfort	considerable	of my present	because of my
		discomfort	bowel pattern	bowel pattern
1	Cor 2	ncentration 3	4	5
I have my normal	I occasionally have	I occasionally have	I usually have	I just can't seem
ability to	trouble	considerable	considerable	to concentrate at
concentrate	concentrating	trouble	difficulty	all
		concentrating	concentrating	

Appendix F: Symptom Distress Scale

Degrees of Distress

Appearance

	1-1	peurunee		
1	2	3	4	5
My appearance	Occasionally I am	I am not often	Most of the time I	The worsening of
has basically not	concerned about	concerned that my	am concerned that	my physical
changed	the worsening of	appearance is	my physical	appearance is a
	my physical	worsening	appearance is	constant,
	appearance		worsening	preoccupying
				concern
	В	reathing		
1	2	3	4	5
I usually breathe	I occasionally	I often have trouble	I can hardly ever	I almost always
normally	have trouble	breathing	breathe as easily as	have severe
	breathing		I want	trouble with my
				breathing
		Outlook		
1	2	3	1	5
I am not worried	I am slightly	I am worried and	I am very worried	I am terrified by
or frightened	worried but not	frightened about	and frightened	thoughts of the
about the future	frightened about	things	about things	future
about the future	things	unings	about tilligs	Tuture
	unngs			
		Cough		
1	2	3	4	5
I seldom cough	I have an	I often cough	I often cough, and	I often have
	occasional cough		occasionally have	persistent and
			severe coughing	severe coughing
			spells	spells

Appendix G: Mini-Mental State Exam

Mini Mental

Claimant Name:		
MENTAL STATUS EVALUATION		
Mini-Mental State Examination (MMSE) Folstein, et a	1, 1975	
	Max Points	
Assessor: Write applicant's responses in each blank	Per Item	Score
ORIENTATION	1	
1. What is the year?	1	
Date	i	
Day	1	
Month	1	
2. Where are we? State	1	
County	1	
Town or City	1	
Street Address Floor (or room in house)	i	
Ploof (of foolif in flouse)		
REGISTRATION		
3. Name three objects (e.g. book, lamp, tree) taking one second to say each.		
Ask the applicant to repeat all three after you have said them once. Give one point		
for each correct answer. Before proceeding, repeat the words until the applicant learns all three. Record the words below:		
learns all three. Record the words below:	3	
ATTENTION AND CALCULATION (Do either A -or- B counting or spelling. Do	not do partial ansv	wers or switch)
4. A. Begin with 100 and count backwards by 7. Stop after five answers.		,
(Correct response = 93, 86, 79, 72, 65)	5	
Give one pint for each correct answer,,,) 3	
-OR-		
B. Spell world backwards (d l r o w),,,		
RECALL		
5. Ask for names of three objects learned in question #3. Give one point for each		
Correct answer.		
	3	
T I NOVI I OD		
LANGUAGE 6. Show a pencil and a watch. Have applicant name them as you point.		
Point to Pencil	1	
Point to Watch	1	
7. Have the applicant repeat: "No ifs, and's, or but's"	1	
8. Have the applicant follow a three-stage command:		
"Take a paper in your right hand; fold it in half; put it on the floor."	3	
Instructions for questions 9-11 on following page.		
9. Have the applicant read and obey the following words: "CLOSE YOUR EYES"		
(See next page)	1	
10. Have the applicant write a sentence.		
(The sentence should contain a subject and a verb and make sense. Ignore spelling		
when scoring) Sentence should be written on the next page.	1	
11. Have the applicant copy the design on the next page. (Give one point if all sides	1	
and angles are preserved and if the intersecting sides form a quadrangle.) Design should be drawn on the next page.	1	
Design should be drawn on the next page. Total Score After Visit	Total Score	/30

2 of 11

Assessor's	Initiale	

Appendix G: Mini-Mental State Exam

Mini Mental

	Claimant Name:
	MENTAL STATUS EVALUATION Mini-Mental State Examination (MMSE) Folstein, et al, 1975
QUESTION #9:	
HAVE THE CLA	AIMANT DO THIS:
	CLOSE YOUR EYES
	•
QUESTION #10	
	AIMANT WRITE A COMPLETE SENTENCE HERE:
QUESTION # 11 HAVE THE CLA	AIMANT COPY THIS DESIGN HERE:
(The copy of this design sh	hould consist of two intersecting five sided figures. The applicant has <u>one</u> chance to copy the design.
IDENTIFY IF CLAIMA	NT HAS ANY PHYSICAL LIMITATIONS EFFECTING FOLSTEIN SCORE:
And the second s	

Appendix H: Demographics Questionnaire

IDENTIFICATION NUMBER

Interview site: 1=Home 2=Office 3=Other

BASELINE DATA

1. Age:

- 2. Gender:
- 1=Male 2=Female
- 3. Ethnicity

1= White, Non-Hispanic 2= African-American 3=Hispanic 4=Oriental 5=Other

- 4. Marital status:
- 1=Married 2=Single 3=Widowed 4=Divorced
- 5. Educational level:

1= 8th Grade or Less 2=Some High School 3=High School Graduate 4=Some College/Vocational Training 5=College Graduate 6= Post Graduate/Professional

6. Current residence:

1=Private Home 2=Apartment 3=Hotel 4=Retirement Residence 5=Other

7. Do you smoke?

1=Yes 2=No

If yes, how many pack per day?

1=1 2=2 3=3 4=4 5=5 6=more than 6 per day 7=N/A

If yes, how many years have you smoked?

1=1-5yrs 2=6-10yrs 3=11-15yrs 4=16-20yrs 5=21-25yrs 6=26-30yrs 7=more than 30 yrs 8= N/A

8. Documented Arrhythmia at time of arrest

1=Pulseless Ventricular Tachycardia 2= Ventricular Fibrillation 3=Bradycardia

4= Asystole 5=Ventricular Tachycardia with a pulse 6=Other

9. Length of arrest time

1=less than 1 min 2=1-3 min 3=4-6 min 4=7-10mins 5=11-15mins 6=greater than 15 min

10. History of CAD, past MI, or arrest.

1=CAD 2=MI 3=Arrest 4=1,2 5=1,2,3 6=N/A

11. History of CHF

1=Yes 2=No

If yes, NYHA Classification

1=I 2=II 3=III 4=IV 5=N/A

12. Ejection Fraction

1=5-10% 2=11-15% 3=16-20% 4=21-25% 5=26-30% 6=31-35% 7=36-40% 8=41-45% 9=46-50% 10=51-55% 11=56-60% 12=61% or greater 13= Don't Know

13. Length of stay in hospital

1=1-3days 2=4-6days 3=7-10days 4=11-14days 5=greater than 14 days

14. In hospital arrest or out of hospital arrest

1=In-hospital 2=Out-of-hospital

15. Time since the arrest

1= 1month 2= 2months 3=3months 4=4months 5=5months 6=6months

7=7months 8=8months 9=9months 10=10months 1=11months

12=12months

16. WT

1=120-130 lbs 2=131-140 lbs 3=141-150 lbs 4=151-160 lbs 5=161-170 lbs

6=171-180 lbs 7=181-190 lbs 8=191-200 lbs 9=201-210 lbs 10=211-220 lbs

11=221-250 lbs 12=greater than 250lbs

17. HT

1=60-65 inches 2=66-70 inches 3=71-75 inches 4=76-80 inches

Appendix I: Qualitative Interview Cardiac Arrest Subjects

1. What one significant thing has changed in your life since your event?

- "I have a second start at life. I stop to smell the roses. I look now at my diet and ways to live healthier, but sometimes it's difficult due to the medications I'm on." "Something that might be important is in the first seven days in the hospital I had a sense of paranoia, like somebody was out to get me." "I questioned the nurses when they came in to change my IV bag or give me medications, but I don't have that feeling now."
- "I look at my children longer. I don't know what they would have done if I were gone." "I enjoy each day I have with my family"
- "I don't have the energy that I had before." "I'm very careful at things I do around the house."
- "Don't take life for granted." "You can be here one minute and gone the next." LVAD pt
- "My general habits have changed considerably." I have stopped smoking and drinking." I am more aware of what I eat."
- "Although I'm slow at getting around, I take time each day as a new day." "I might be 70 years old, I still have some life left in me."
- "Things I eat. I watch everything I eat. I make sure they are healthy." "My taste is different, foods taste different for me since my arrest." "I can't taste some things that I could before."
 - 2. What significant change in your lifestyle or physical activity has occurred since your event?
- "Like I said before I look at my diet and my activities I do daily." "I make sure if I am not at work, I'm doing something that requires walking or being outside."
- "I try to be as active as I can doing things with my family." "I would like to get back to playing golf, but I don't think I'm up to that yet." "I still have a lot of nausea with the medications I'm taking."
- "I don't go out as much with my family, like going out to eat." "When I feel like I have the energy is usually when I'll call my daughter and say I would like to go somewhere and she drives me."

- "Take care of yourself, you can't take care of others if your sick." "Not as active as I use to be and carrying these batteries around can make you tired." LVAD pt.
- "Since my event, I see it as a great opportunity to change my life." "Like I said before, I stopped the bad habits that I had."
- "I have not really changed my life style and do about the same physical activity as before my experience."
- "I am limited in my physical activity because of my back. I had previous back injury and take medications for that as well as make frequent visits to the pain clinic"
 - 3. Since your event you have come in contact with several healthcare professionals, nurses, doctors and other healthcare personnel. What did you find to be the most helpful with these encounters and what changes would you recommend improving communications?
- "Probably listening to me as I have said to the doctor several times about my medications, they just upset my stomach." "The medics in the field knew exactly what was happening and acted quickly." "The doctors and nurses I met on the way back to the states were fantastic." "A great system that works." Helo pilot deployed in Iraq, cardiac arrest while flying helo, crashed helo.
- "I wish the doctor would listen to me more. I tell him about the nausea from the medications and all he says I need to take them, it will go away." "The nurses that took care of me in the ICU were great." "They were great to me and my family." "I still see them since I work here, so I see them when I make rounds."
- "The most helpful was just having someone explain to me all the medical terms that I didn't understand." "I'm on allot of medications and sometimes it can be confusing." "Just make sure the nurses and doctors explain what's happening."
- "I wouldn't change a thing, besides what happen to me, but everybody was great during my stay." "I wouldn't change a thing."
- "Slight advantage, wife works in the industry." "English speaking would have been good." "Specifically cardiologist spoke another language, needed someone to turn to for explanation of what he said." "Language barrier big problem."
- "Make sure you talk and explain what is going on." "I think that was scary for me as sometimes, I did not understand some of the medical terms."
- "The nurses and doctors have been great, I can't say enough about them." "I owe them allot." "They saved my life and I'm grateful."

Appendix J: Qualitative Interview Non-Cardiac Arrest Subjects

1. What one significant thing has changed in your life since your event?

- "Shortness of breath, I see the doctor soon, Monday." "They attribute to the hole in the mitral valve." "It has dramatically impacted by walking up and down stairs and the problem is I live in a two story house."
- "I have slowed down quite a bit and get tired easy." "I'm going to my cardiologist and surgeon." "I have numbness in the toes on both feet and it is the leg where they took the graft for my bypass."
- "More aware of chest pain symptoms." "I monitor my health more closely." "I am more aware of what things I eat."
- "More specific was the stoke I had, I can't go places like I use to." "Me and my wife traveled six months out of the year, but not as much now." "It's my physical abilities, can't do as much."
- "A lot more serious outlook on life." "I had my wake-up call." "I have learned don't take things for granted."
- "My wife says I bitch a lot." "I have slowed down, don't do as many things as use to do." "I think it's mental, misgivings things like that, it's really been the last 5 years.
 - 2. What significant change in your lifestyle or physical activity has occurred since your event?
- "I can do certain things." "Two days a week I work at the park and service center with the children." "What I do has changed to a certain point, I have to sit down more often, but that's okay, I am answering phones, it helps and I like doing it."
- "Difficult time walking, in general." "I use a cane just for stability, not walking."
- "I have increased level of exercise significantly." "I try to eat less fat, improve what I take in." "Realized I needed to change for the better."
- "Use to walk 5 miles, now only walk about a mile or mile and a half." "On the go all the time." "Still weak, I know my limitations, that's just part of living."
- "A little more serious about diet." "Experience has changed a majority of my life." "I realized things could change anytime."
 - 3. Since your event you have come in contact with several healthcare professionals, nurses, doctors and other healthcare personnel. What did you find to be the most

helpful with these encounters and what changes would you recommend improving communication?

- "Doctor is fine, nurses I have not had as much communication" "No recommendations, good relationship with regular doctor and cardiologist."
- "Seminar I attended I attend had a lot of information, very helpful, all cardiac patients were there." "Nurses particularly rehab very good." "I have no memory of the first 3 weeks in the hospital, but the first thing I remember was going to rehabilitation." "No improvements, everybody has been great, Intensive care was great to my wife."
- "Cardiac rehab instrumental in giving positive outlook, one on one and the peer participation." "Difficult to talk with cardiologist, too many gates to go through." "Shouldn't be like that, they can at least take 30 seconds to talk to you."

I have had the best treatment, like my primary, cardiologist and therapist, couldn't ask for anything else, communication excellent."

- "Please when doctor noticed changes in my EKG, that made a difference in my life." "Waiting time for appointments, wouldn't want to make this an issue."
- "One particular cardiologist, he was not telling me everything, what was going on with me." "I changed doctors, I improved, I was treated like something was wrong with me."

Appendix K: IRB Approval University of San Diego



Institutional Review Board

Project Action Summary

Action Date: Fel	Note: Approval expires one year after this date.
Type:New Fu	all Review _X_New Expedited ReviewContinuation ReviewExempt ReviewModification
Action: _2	X_ApprovedApproved Pending ModificationNot Approved
Project Number: Researcher(s):	John J. Whitcomb Doc SON Allen Orsi Fac SON
Project Title:	Descriptive Study of Functioning Among Post cardiac Arrest Survivors Discharge Home
ultima	nd IRB correspondence regarding student research to the faculty advisor, who bears the te responsibility for the conduct of the research. We request that the faculty advisor this correspondence with the student researcher.
Modifications R	equired or Reasons for Non-Approval
None	
	e for submitting project proposals to the Provost's Office for full review is _N/A You ject proposal for expedited review at any time.
Dr. Thomas R. H. Administrator, In herrinton@sandie	stitutional Review Board
5998 Alcalá Park	

Appendix L: IRB Approval Sharp Cardiac Rehabilitation Center



June 8, 2005

John J. Whitcomb, PhD (c), RN, CCRN 1324 Granite Springs Drive Chula Vista, CA 91915

RE:

A Descriptive Study of Functiong in Post Cardiac Arrest Survivors Discharged Home, IRB# 050682

Dear Dr Whitcomb:

This is notification that you have been granted expedited approval by the Sharp HealthCare Institutional Review Board (IRB) of your application, for the above-referenced research study. This action will be reported to all committee members at the June 15, 2005 meeting.

The following site and investigators are approved:

Site:

Memorial

Principal Investigator: John Whitcomb, PhD(c), RN, CCRN

Sub-investigator: Miller, Mary E. MA

Your IRB approval reference number is 050682. Please include this reference number in all of your future correspondence and reporting to the IRB Office. As a reminder, it is the responsibility of the principal investigator to submit status reports to the Institutional Review Board. Your IRB approval expires Friday, June 16, 2006 you must submit a status report by Friday, May 5, 2006 or changes to the protocol or informed consent document, please submit them to the Institutional Review Board for approval. In addition, all patient recruitment materials must be submitted to the Board for approval prior to their use.

It is the policy of Sharp HealthCare Institutional Review Board that the Principal Investigator(s) submit a copy of their reports, findings, or manuscripts to the Board prior to publication. Sharp HealthCare would expect that if the results of the research project came to publication, their role would be properly recognized in the research.

Please contact the IRB Office if you should have any questions at (858) 499-4836.

Sincerel

David Bodkin, M.D.

Chair, Institutional Review Board

Sharp HealthCare

SHARP ORGANIZATIONS

8-2

San Diego Hospital Association

Sharp Memorial Hospital

Grossmont Hospital Corporation

Sharp Chula Vista Medical Center

Sharp Coronado Hospital and HealthCare Center

Sharp Mesa Vista Hospital

Sharp Mary Birch Hospital For Women

Sharp Vista Pacifica

Sharp Mission Park Medical Centers

Sharp Rees-Stealy Medical Centers

Sharp Health Plan

SCMC Corporation

Sharp HealthCare Foundation

Grossmont Hospital Foundation

Coronado Hospital Foundation

8695 Spectrum Center Boulevard

San Diego, California 92123-1489

Appendix M: Consent Form University of San Diego

Consent Form

John Whitcomb is conducting an investigation in describing functional status in adults who survive a cardiopulmonary arrest, an event where the heart stops and is restarted, within 6 months after discharge to home. Since you have agreed to participate in this study, you understand that you will be completing 4 questionnaires; the SF-36 Health Survey, a Demographic Data Questionnaire, Mini-Mental Questionnaire and the Symptom Distress Scale and wearing the NewLifestyle-2000 (NL-2000) Activity Monitor for 7 days

Initial interview with Mini-Mental Sate Exam, Demographics Questionnaire and explanation of wearing the NL-2000 Activity monitor will take approximately 40 minutes. After enrolled you will be recording in a notepad provided, the daily energy expenditure reading from the NL-2000 for 7 consecutive days. At the end of 7 days you will then complete the SF-36 General Health Survey and the Symptom Distress Scale either by phone or in person with John Whitcomb, which takes approximately 20 minutes. Participation in the study should not involve any added risks or discomfort to you except for possible anxiety that may result from the items in the questionnaires. There is no direct benefit by participating in this study, but possible future benefits from you participating in this study include description of functional status in those who survive cardiocal arrest and description of the energy expenditure of those who survive a cardiac arrest and description of the energy expenditure of those who survive a cardiac arrest by use of the NL-2000 Activity Monitor.

Your participation in this study is entirely voluntary. You understand you may refuse to participate or withdraw at any time without suffering any consequences.

You understand the research records will be kept completely confidential. Your identity will not be disclosed without consent required by law. You further understand that to preserve your anonymity, only group data will be used in any publication of the results of this study.

John Whitcomb has explained this study to you and answered your questions. If you have other questions or research-related problems, you can reach John Whitcomb at (619) 948-4564 or Dr Allen Orsi at (619) 260-4688

There are no further agreements, written or verbal, related to this study beyond that expressed on this consent form. I have received a copy of this consent document and "The Experimental Subject's Bill of Rights".

I have read and understood this form, and consent to the research it describes to me.

Signature of Subject	Date
Signature of Witness	Date
Signature of Researcher	Date

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JUN 0 8 2005

INFORMED CONSENT Institutional Review Board Sharp Healthcare

A Descriptive Study of Functional Status in Post Cardiac Arrest Survivors Discharged Home: Myocardial Infarction (Heart Attack) as a Comparison Group Actively Engaged in Cardiac Rehabilitation

USD-2005-02-028/IRB Number 050682

PRINCIPAL INVESTIGATOR:

John J Whitcomb, PhD(c),RN, CCRN, 1324 Granite Springs Dr, Chula Vista CA 91915, 619-934-4849, University of San Diego, Hahn School of Nursing and Health Science

SPONSOR:

University of San Diego Hahn School of Nursing and Health Science 5998 Alcala Park San Diego CA 92110-2492

Rev. 02/04

APPROVED

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IRB #_050682 Page 2 of 7

A Descriptive Study of Functional Status in Post Cardiac Arrest Survivors Discharged to Home: Myocardial Infarction (Heart Attack) as a Comparison Group Who are Actively Engaged in Cardiac Rehabilitation

Participation in a Research Study

You are being asked to participate in this research study because you have experienced a heart attack (myocardial infarction) and are currently receiving cardiac rehabilitation. Your participation is voluntary. Please read this consent form and ask the researcher any questions you may have about the study. If you do not want to participate in the research study you will still receive the standard of care that you would without your participation in this research study. Please take your time to make your decision. Discuss it with your friends and family.

Why Is This Study Being Done?

The purpose of this study is to examine the relationship of physical activity(physiological),emotional (psychological) and family(situational) factors on how you function after a heart attack (myocardial infarction). You will be asked to complete a demographics questionnaire, Mini-Mental State Exam, Symptom Distress Scale and a Standard General Health Questionnaire. Your answers to these will help to see how you are functioning after experiencing you heart attack and how you are functioning with your rehabilitation. The total time required to complete the questionnaires is about 45 minutes.

The demographics, and Mini-Mental State Exam will be given to you initially. The Symptom Distress Scale and Standard Form General Health Survey you make take and complete at home and return to me.

What Is Involved in the Study?

On the first day you will be given a New Life Style Activity Monitor (NL-2000). The NL-2000 Activity Monitor, which is small 1 inch X 2 inches, provides the user an idea of the calories they burn throughout the day or week. You will provide your age, gender, height and weight, and the monitor will determines their basal metabolic rate (BMR). This will tells you how many calories your body needs to keep functioning properly and the intensity of your activity (the higher the intensity, the more calories the unit will register). The researcher will assist you in setting up the monitor which is worn on you belt or pants at hip level. You will wear this device for 7 days, and each day will be recorded in the memory of the monitor. On the 7th day the information will be collected (the number of steps you did each day) and the Symptom Distress Scale and Standard health Form will be collected that same day. You will also be asked three questions:

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Institutional Review Board

IRB #_050682 Page 3 of 7

- 1. What one significant thing has changed in your life since your heart attack?
- 2. What significant change in your lifestyle or physical activity has occurred since your heart attack?
- 3. Since your heart attack you have come in contact with several healthcare professionals, (nurses, doctors and other health care professionals). What did you find to be the most helpful with these encounters and what changes would you recommend to improve communications?

How Many People Will Take Part in the Study?

The expected number of to be enrolled at Sharp Cardiac Rehabilitation at Sharp Memorial Hospital is 7.

How Long Will I Be in the Study?

You will be in the study for 7 days. Your participation in this study is entirely voluntary. You may refuse to participate or withdraw at any time without suffering any consequences.

What Are the Risks of the Study?

Participation in the study should not involve any added risks or discomfort to you except for possible anxiety that may result from the items in the questionnaires.

Minimal risks or discomforts are anticipated related to their participation in this study. If however, during the interview you become tired, you will be provide opportunity to rest if you desire. When answering the questions related to your mental or physical health, you may experience emotions of sadness. Support will be provided and if further assistance is needed, such as a referral to a mental health professional (such as the San Diego County Mental Health Hotline).

Special Considerations of the Study?

There are no special consideration for this study.

Are There Benefits to Taking Part in the Study?

Although it is hoped that you will benefit from participation in this study, we cannot guarantee that your participation will directly benefit you. It is hoped that this research may benefit other patients in the future.

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IRB #_050682 Page 4 of 7

What Other Options Are There?

There are no alternative therapies, only that you choose not to voluntarily participate and continue cardiac rehabilitation as prescribed per your healthcare provider.

What About Confidentiality?

All of your information will be identified by numbers. You r name will not appear on any of the data collection tools. You information will be kept in a locked file cabinet in the researcher's office, with access only by either the student or advisor. All data will be kept a minimum of 5 years before being destroyed.

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include the following groups: the United States Food and Drug Administration (FDA), the Sharp HealthCare Institutional Review Board (IRB), the Site Management Organization (SMO), and the Office for Human Research Protections (OHRP) .

Protected Health Information (PHI)

Your health information will not be used for this study.

What Are the Costs?

There are no costs to you for participating in this study. The NL-2000 Activity Monitors will be provided at no charge to you or your insurance company. At the end of your participation in the study you will be given the activity monitor as a gift for your participation and \$25.00 for your time and efforts.

Research Related Injury?

When answering the questions related to your mental or physical health, you may experience emotions of happiness or sadness. Support will be provided and if further assistance is needed, a referral to a mental health professional or appropriate services via the cardiac rehabilitation staff as needed. Sharp HealthCare will not provide any compensation to you in the event of a research related injury.

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124

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JUN 0 8 2005

Institutional Review Board Sharp Healthcare IRB #_050682 Page 5 of 7

What Are My Rights as a Participant?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Any new study information regarding your health, welfare or willingness to participate will be made available to you.

Whom Do I Call If I Have Questions or Problems

For questions about the study or a research related injury, contact the researcher John J Whitcomb at 619-934-4849 or 619-948-4564.

For questions about your rights as a research participant or to address complaints about the research, contact David J. Bodkin, M.D., Chair of the Sharp HealthCare Institutional Review Board (a group of people who review the research to protect your rights) via the:

Sharp's Office for the Protection of Research Participants (IRB) 8695 Spectrum Center Boulevard San Diego, California 92123 Phone: (858) 499-4836

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IRB #_050682 Page 6 of 7

Signature

Your signature below indicates that you have read the above about your participation in this study completing 4 questionnaires, answering 3 questions and wearing the NL-2000 Activity Monitor for 7 days and have had a chance to ask questions to help you understand what your participation will involve. You agree to participate in the study until you decide otherwise. You are not waiving your legal rights by signing this consent form.

Signature of Subject (or Legally Authorized Representative	Printed Name	Date
Signature of Witness	Printed Name	Date
(Note: The IRB must give approval for Investigator or the Co-Investigator(s) t must submit CVs and conflict of interest.)	o obtain consent from sub	jects. These individual
I <u>John J Whitcomb</u> attest that the requiresearch project described in this form provided with a copy of the Experimenthe research project with the participant terms all of the information contained and adverse reactions that may reasonate encouraged the participant to ask questions.	have been satisfied – that ntal Subject's Bill of Right and explained to him or in this informed consent for ably be expected to occur.	the participant has been ts, that I have discussed her in non-technical form, including any risks I further certify that I
Signature of Investigator	Printed Name	Date
This consent document expires on _		

Appendix O: California Experimental Subjects Bill of Rights

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Institutional Review Board Sharp Healthcare

CALIFORNIA EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in an experimental procedure. Before you decide whether you want to participate in the experimental procedure, you have a right to:

- 1. Be informed of the nature and purpose of the experiment;
- Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- Be given a description of any discomforts and risks reasonably to be expected from your participation in the experiment;
- Be given an explanation of any benefits reasonably to be expected from your participation in the experiment;
- Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to you, and their relative risks and benefits;
- Be informed of the avenues of medical treatment, if any, available to you after the experimental procedure if complications arise;
- Be given an opportunity to ask any questions concerning the medical experiment or the procedures involved;
- Be instructed that consent to participate in the experimental procedure may be withdrawn at any time and that you may discontinue participation in the medical experiment without prejudice;
- 9. Be given a copy of this form and the signed and dated written consent form; and
- Be given the opportunity to decide to consent or not to consent to the medical
 experiment without the intervention of any element of force, fraud, deceit, duress,
 coercion or undue influence on your decision.

I have carefully read the information contained above and I understand fully my rights as a potential subject in a medical experiment involving people as subjects.

Signature of Subject	Signature of Witness
Date	Date